The Pragmatic Airway Resuscitation Trial

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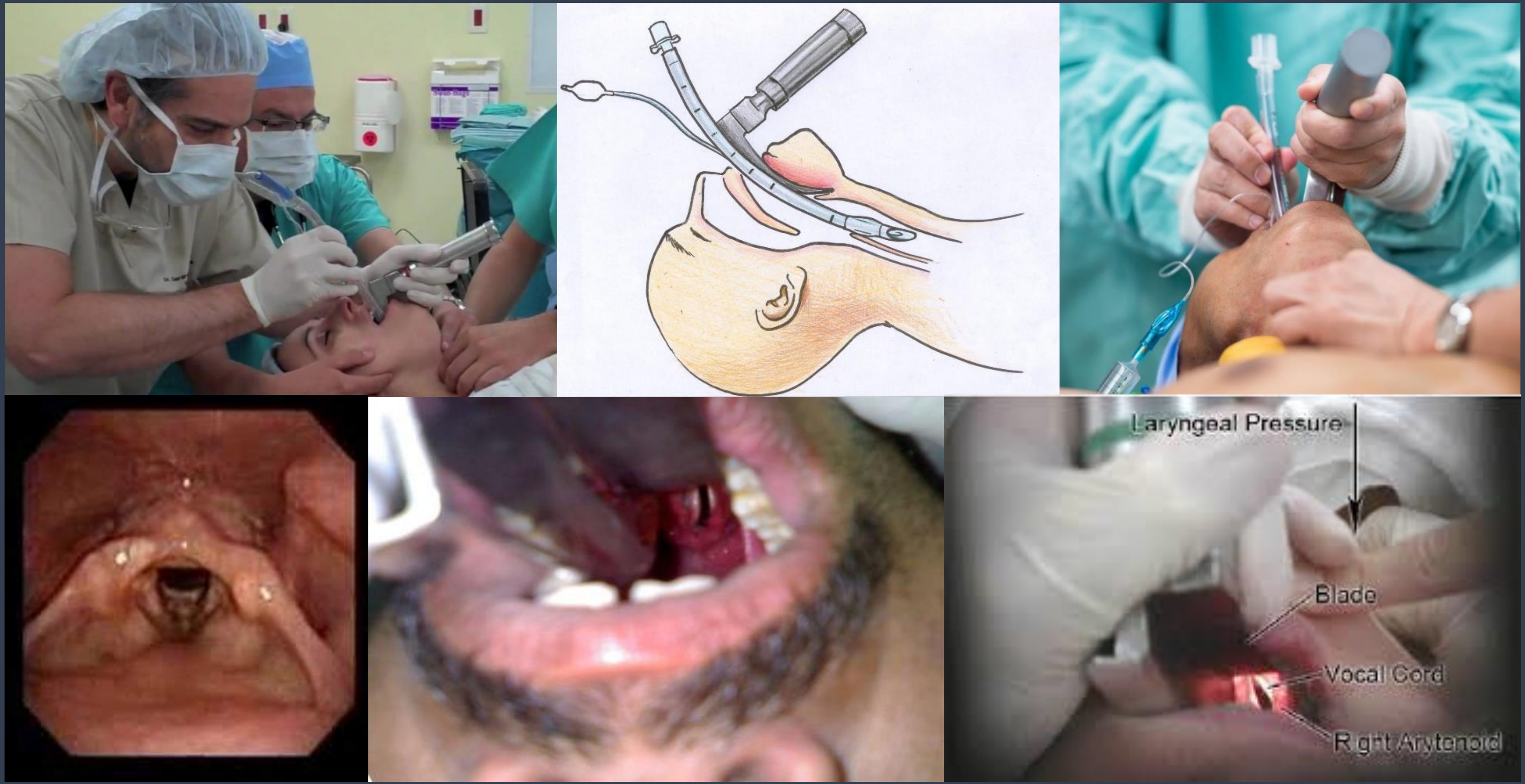
Disclosures

- **NIH Grant Support**
  - UH2/UH3-HL125163
- **PI, Pragmatic Airway Resuscitation Trial**

What is Bag-Valve-Mask Ventilation?

What is Endotracheal Intubation?



What is EMS?

- Emergency Medical Services
- Emergency acute care
- Rapid assessment, stabilization, triage
- Transport to receiving hospital
- Uncontrolled prehospital environment

System of US EMS Care

- **Basic Life Support (BLS) Emergency Medical Technician (EMT)**
  - CPR
  - Bag-valve-mask ventilation
  - Automated external defibrillators
  - No intubation or drugs
- **Advanced Life Support (EMS) Paramedic**
  - Intubation
  - IV medications
  - Manual defibrillation
- **Few EMS physician systems in US**

Why Intubate in the Field?

- Provide direct conduit to lungs
- Improve ventilation
- Prevent aspiration
- Parallels in-hospital care
- Ultimate goal → "Save lives"

www.trauma.org

"Does Prehospital Intubation Improve Outcomes (Save Lives)?"

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Does Intubation Save Lives?

- **>20 studies of prehospital intubation and outcome (survival)**

- **Recurrent theme:**
  - Prehospital intubation associated with *increased* risk of death
  - Prehospital intubation associated with *poorer* neurological outcome

HOUSTON EMERGENCY MEDICINE

Prehospital Intubation of Children

CARING FOR THE CRITICALLY ILL PATIENT

Effect of Out-of-Hospital Pediatric Endotracheal Intubation on Survival and Neurological Outcome

A Controlled Clinical Trial

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Context Endotracheal intubation (ETI) is widely used for airway management of children in the out-of-hospital setting, despite a lack of controlled trials demonstrating a positive effect on survival or neurological outcome.

Objective To compare the survival and neurological outcomes of pediatric patients treated with bag-valve-mask ventilation (BVM) with those of patients treated with BVM followed by ETI.

Design Controlled clinical trial, in which patients were assigned to interventions by calendar day from March 15, 1994, through January 1, 1997.

Setting Two large, urban, rapid-transport emergency medical services (EMS) systems.

Participants A total of 830 consecutive patients aged 12 years or younger or estimated to weigh less than 40 kg who required airway management; 820 were available for follow-up.

Interventions Patients were assigned to receive either BVM (odd days; n = 410) or BVM followed by ETI (even days; n = 420).

Main Outcome Measures Survival to hospital discharge and neurological status at discharge from an acute care hospital compared by treatment group.

Results There was no significant difference in survival between the BVM group (123/404 [30%]) and the ETI group (110/416 [26%]) (odds ratio [OR], 0.82; 95% confidence interval [CI], 0.61-1.11) or in the rate of achieving a good neurological outcome (BVM, 92/404 [23%] vs ETI, 85/416 [20%]) (OR, 0.87; 95% CI, 0.62-1.22).

Conclusion These results indicate that the addition of out-of-hospital ETI to a paramedic scope of practice that already includes BVM did not improve survival or neurological outcome of pediatric patients treated in an urban EMS system.

JAMA. 2000;283:783-790 www.jama.com

ALTHOUGH BAG-VALVE-MASK ventilation (BVM) and endotracheal intubation (ETI) are both widely used in the out-of-hospital setting in caring for critically ill or injured children, there has been no controlled study comparing the outcomes of pediatric or adult patients treated with these 2 procedures. In 1 out-of-hospital study, BVM did compare favorably to non-ETI advanced airway management techniques (pharyngeal tracheal lumen, laryngeal mask, and esophageal tracheal combination esophageal-tracheal tube) among adults and children, as measured by PO_2 and PCO_2 values on arrival in the emergency department (ED), frequency of vomiting, and patient outcome.[1]

There have been a number of descriptive studies of ETI in the out-of-hospital setting. Reported success rates of pediatric ETI vary from 50% to 100%, depending on the patient's presenting illness or injury, the age of the patient, education level of the health care provider, and use of neuromuscular blocking agents to facilitate intubation.[2-10] Major complications of ETI, such as esophageal intubation, have been reported in as little as 1.8% and as many as 17% of pediatric patients in the out-of-hospital setting.[7,10] One study reported an overall complication rate of 22.6%, using succinylcholine to facilitate intubation.[10] Despite the fact that retrospective studies comparing the survival of patients treated with BVM and ETI have generally found no difference, some investigators have suggested that ETI may

For editorial comment see p 797.

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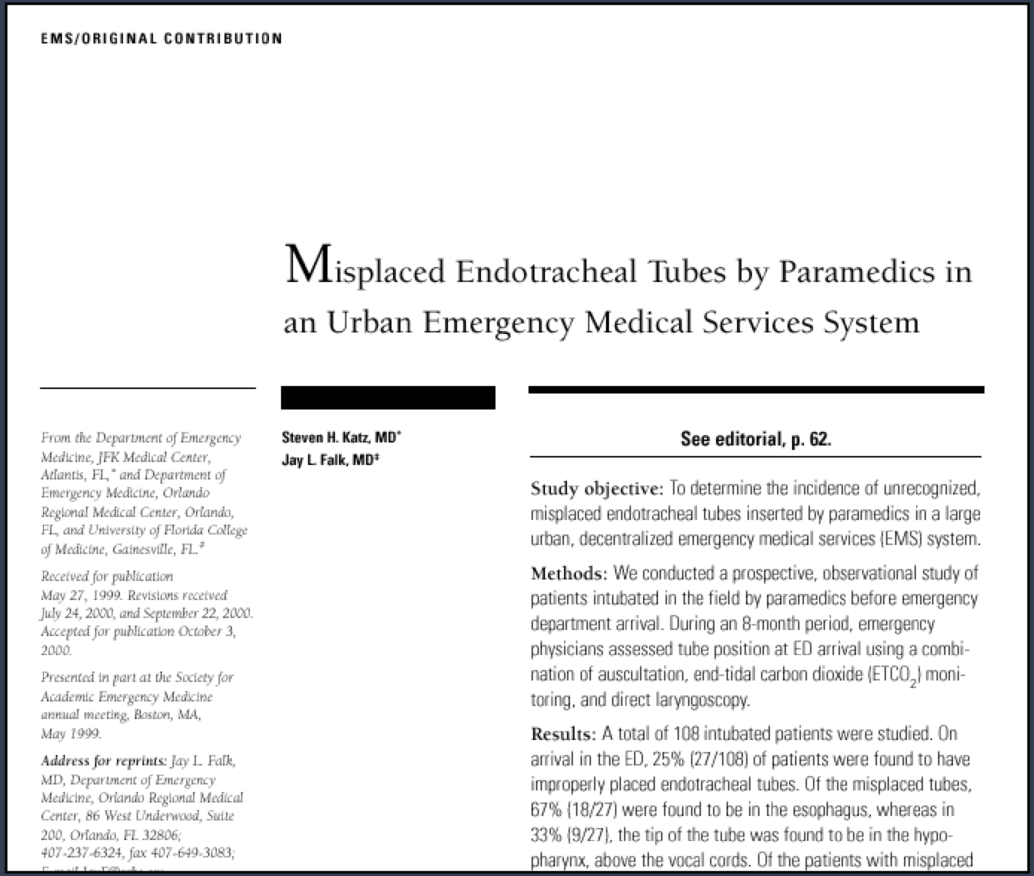
- **Gausche, JAMA 2000**
- **RCT**
- **[BVM ± ETI] vs. BVM-only**
- **830 children**

- **No difference in survival**
- **No difference in neurological outcome**

“Are Poor Outcomes Due to Errors?”

Endotracheal Tube Misplacement

- **Katz and Falk,**
  Annals Emerg Med 1999
- **N=108 prehospital intubations**
  - Systematic reconfirmation in ED
- **<u>25%</u> tube misplacement rate**
  - 2/3 esophageal
  - 1/3 above vocal cords



Misplaced Endotracheal Tubes by Paramedics in an Urban Emergency Medical Services System

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Received for publication May 27, 1999. Revisions received July 24, 2000, and September 22, 2000. Accepted for publication October 3, 2000.

Presented in part at the Society for Academic Emergency Medicine annual meeting, Boston, MA, May 1999.

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See editorial, p. 62.

Study objective: To determine the incidence of unrecognized, misplaced endotracheal tubes inserted by paramedics in a large urban, decentralized emergency medical services (EMS) system.

Methods: We conducted a prospective, observational study of patients intubated in the field by paramedics before emergency department arrival. During an 8-month period, emergency physicians assessed tube position at ED arrival using a combination of auscultation, end-tidal carbon dioxide ($ETCO_2$) monitoring, and direct laryngoscopy.

Results: A total of 108 intubated patients were studied. On arrival in the ED, 25% (27/108) of patients were found to have improperly placed endotracheal tubes. Of the misplaced tubes, 67% (18/27) were found to be in the esophagus, whereas in 33% (9/27), the tip of the tube was found to be in the hypopharynx, above the vocal cords. Of the patients with misplaced

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Oxygen Desaturation and Bradycardia

Incidence of Transient Hypoxia and Pulse Rate Reactivity During Paramedic Rapid Sequence Intubation

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See editorial, p. 729.

Study objective: We determine the incidence of desaturation and pulse rate reactivity during paramedic rapid sequence intubation of patients with severe head injuries (Glasgow Coma Scale score ≤8).

Methods: Adult patients with severe head injuries had recording oximeter-capnometers applied before rapid sequence intubation. Desaturation was defined as a reduction in oxygen saturation (SpO_2) to less than 90% from an initial SpO_2 of greater than or equal to 90% or a decrease from a baseline of less than 90%. Event records were analyzed with emergency medical services (EMS) run sheets and debriefing reports.

Results: Thirty-one (57%) of 54 patients demonstrated desaturation during rapid sequence intubation. Twenty-six (84%) of these 31 events occurred in patients whose initial SpO_2 value with basic airway skills was greater than or equal to 90%. The median duration of desaturation was 160 seconds (interquartile range 48 to 272 seconds), and the median decrease in SpO_2 was 22%. Six (19%) patients experienced marked bradycardia (pulse rate <50 beats/min) during desaturation events. Paramedics described rapid sequence intubation as "easy" in 26 (84%) of 31 patients with desaturation.

Conclusion: Out-of-hospital rapid sequence intubation by paramedics was complicated by a concerning incidence of desaturation and bradycardia. Paramedic reports did not reflect the presence of these concerning derangements. Most patients had acceptable SpO_2 values before rapid sequence intubation. An effective strategy for preoxygenation is needed before it can be concluded that rapid sequence intubation is of value in the out-of-hospital care of patients with serious closed head injury.

[*Ann Emerg Med.* 2003;42:721-728.]

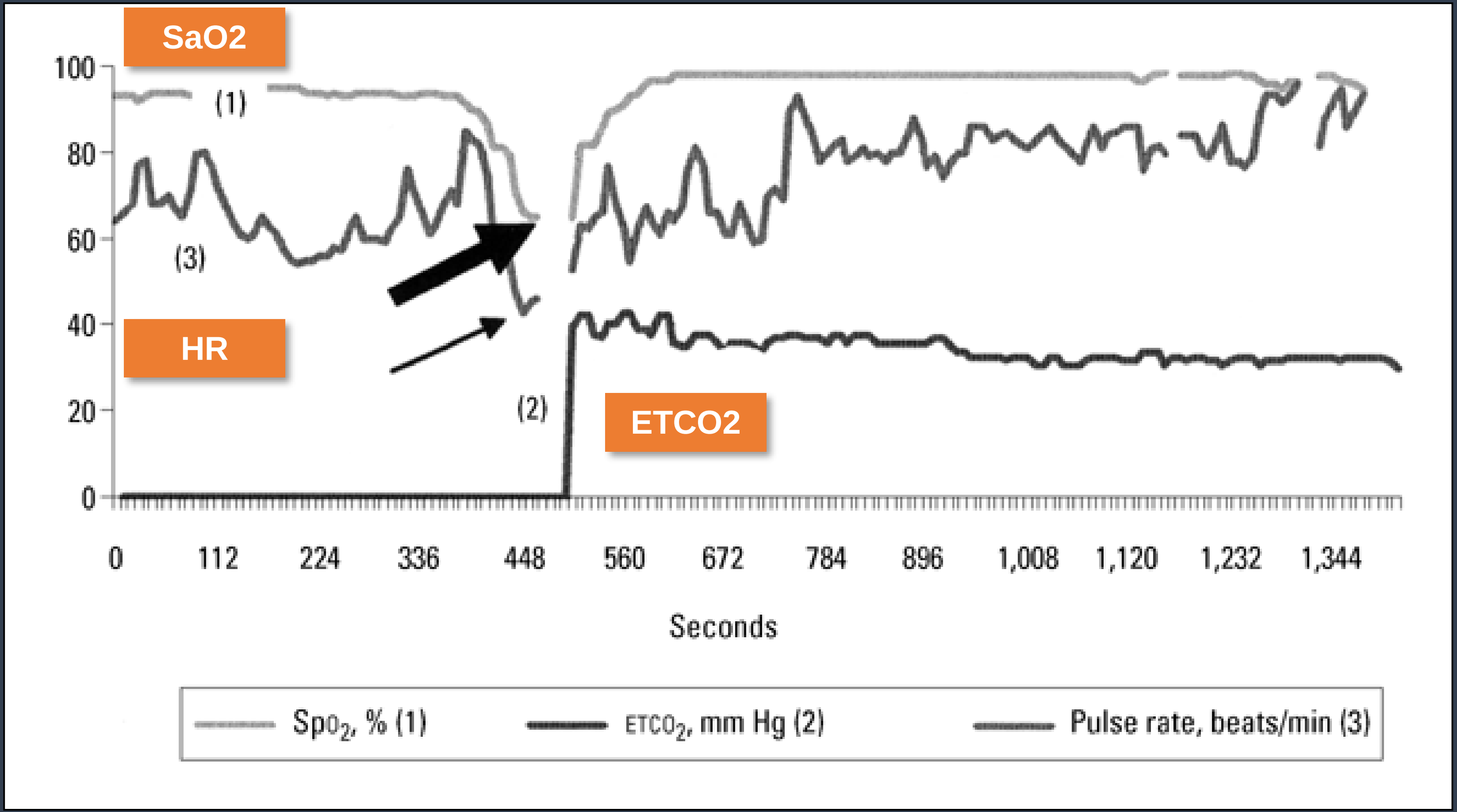
INTRODUCTION

Outcomes from severe closed head injury are related to primary and secondary injury. Immediate damage to neurologic structures can be compounded by a cascade of events resulting in delayed neuronal death. The central nervous system has a high rate of oxygen consumption and lacks alternate energy reserves. Hypotension and hypoxia have been linked to worsened outcomes, and preservation of cerebral perfusion and oxygenation is essential.[1-3]

*0196-0644/2003/$30.00 + 0
doi:10.1016/mem.2003.393*

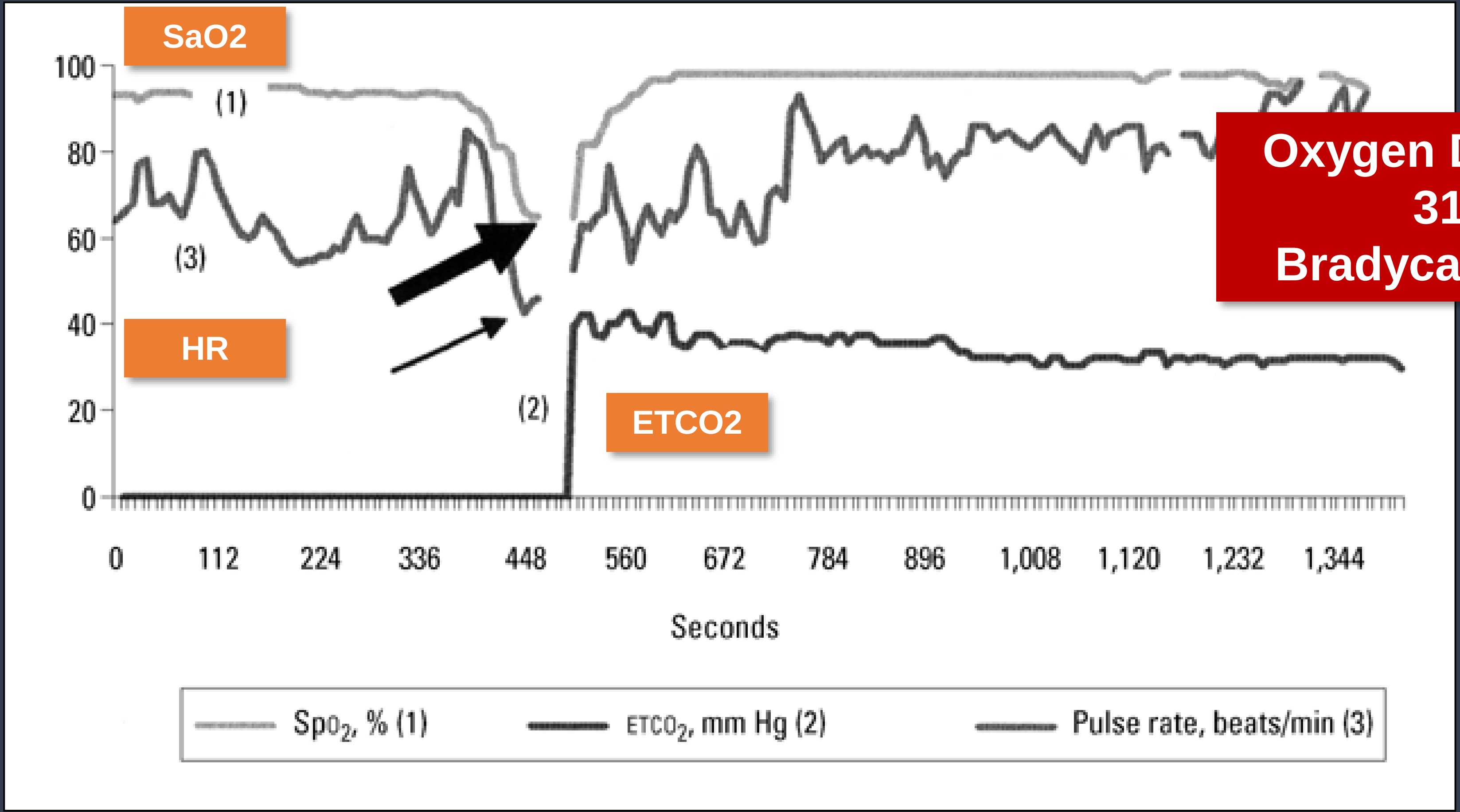
- **Dunford,**
  Annals Emerg Med 2004
- **San Diego RSI Trial**
- **N=152 RSI patients**
- **Continuously recorded waveforms:**
  - Heart Rate
  - Oxygen Saturation
  - End-Tidal Capnography

Oxygen Desaturation and Bradycardia



Dunford, et al. Ann Emerg Med 2004

Oxygen Desaturation and Bradycardia



Oxygen Desaturation: 31 (57%) Bradycardia: 6 (19%)

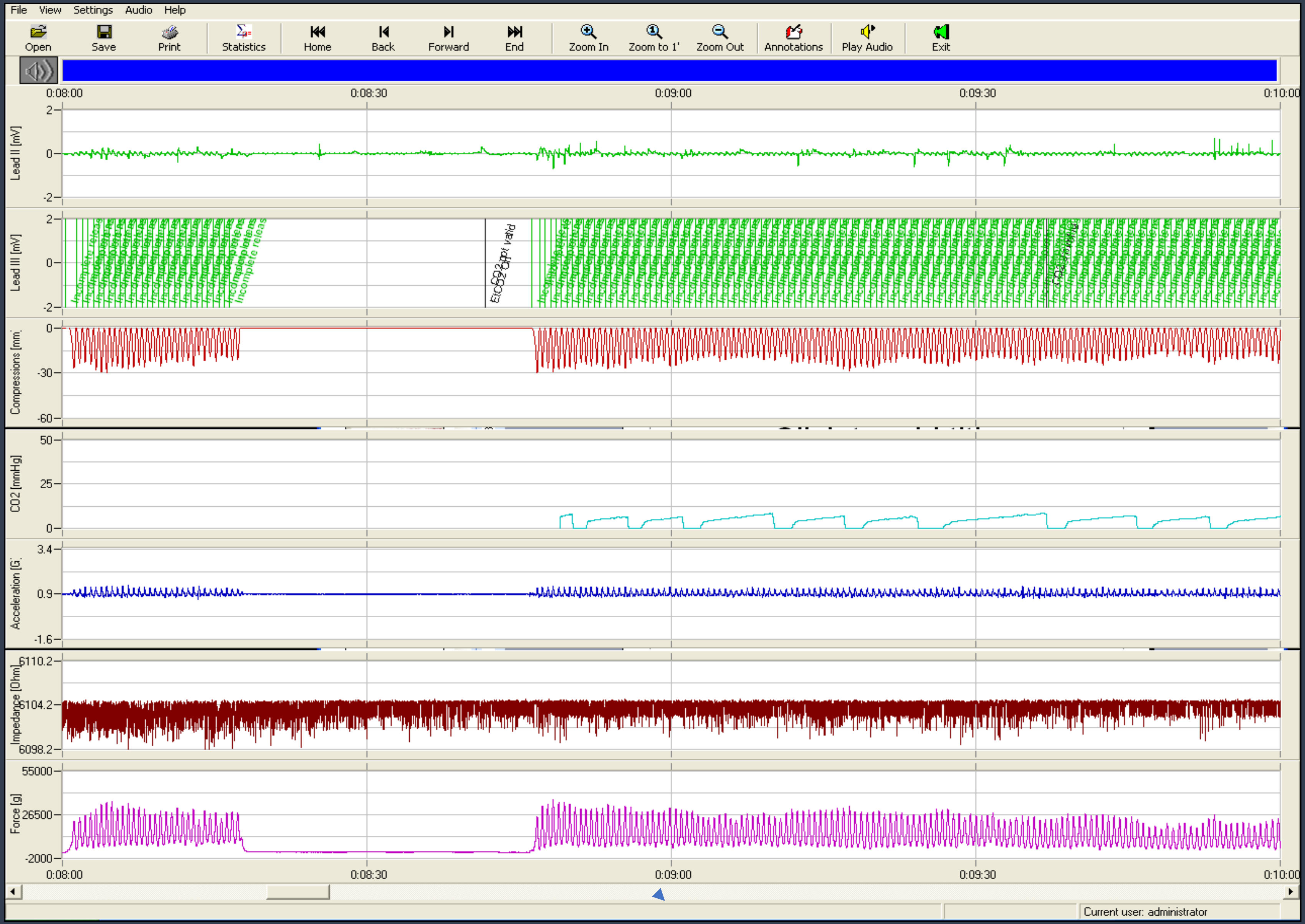
Dunford, et al. Ann Emerg Med 2004

“Does Intubation <u>Interact</u> with Other Interventions?”

CPR Chest Compressions

- **ACLS Guidelines:**
  - ***"Avoid CPR Chest Compression Interruptions"***
- **New CPR detection technology**
  - Can "see" delivered chest compressions

Example of CPR Interruption from Intubation



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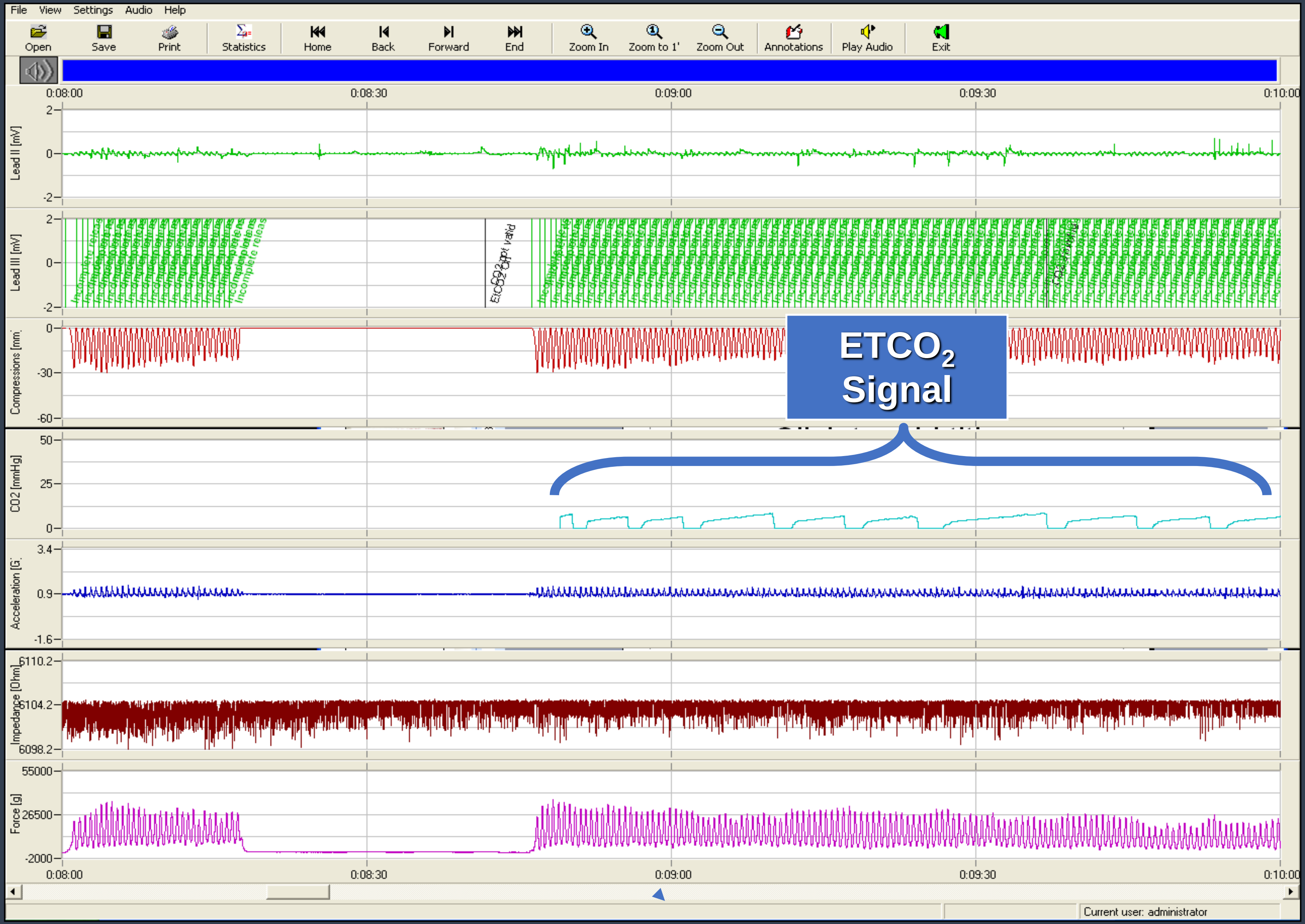

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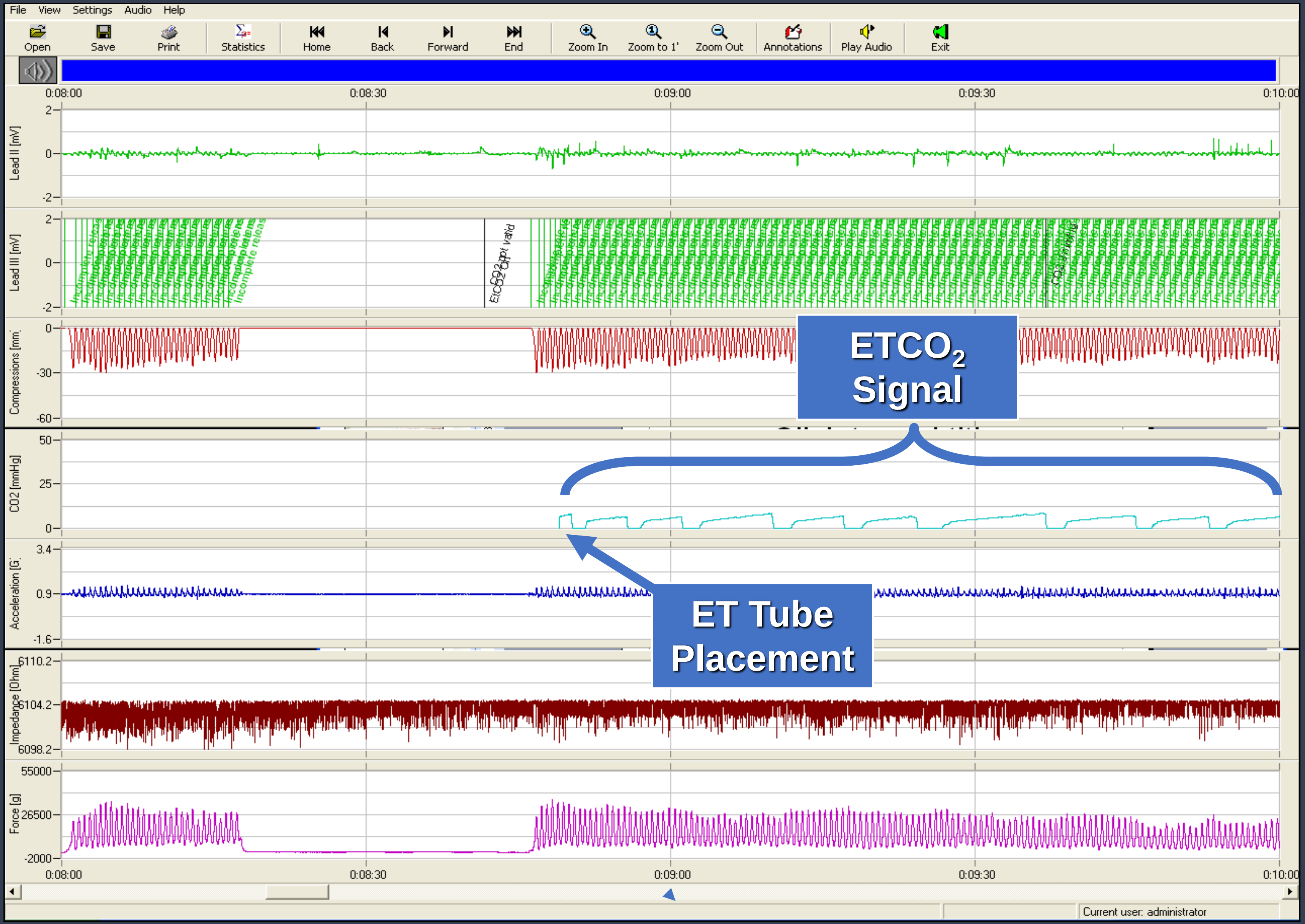

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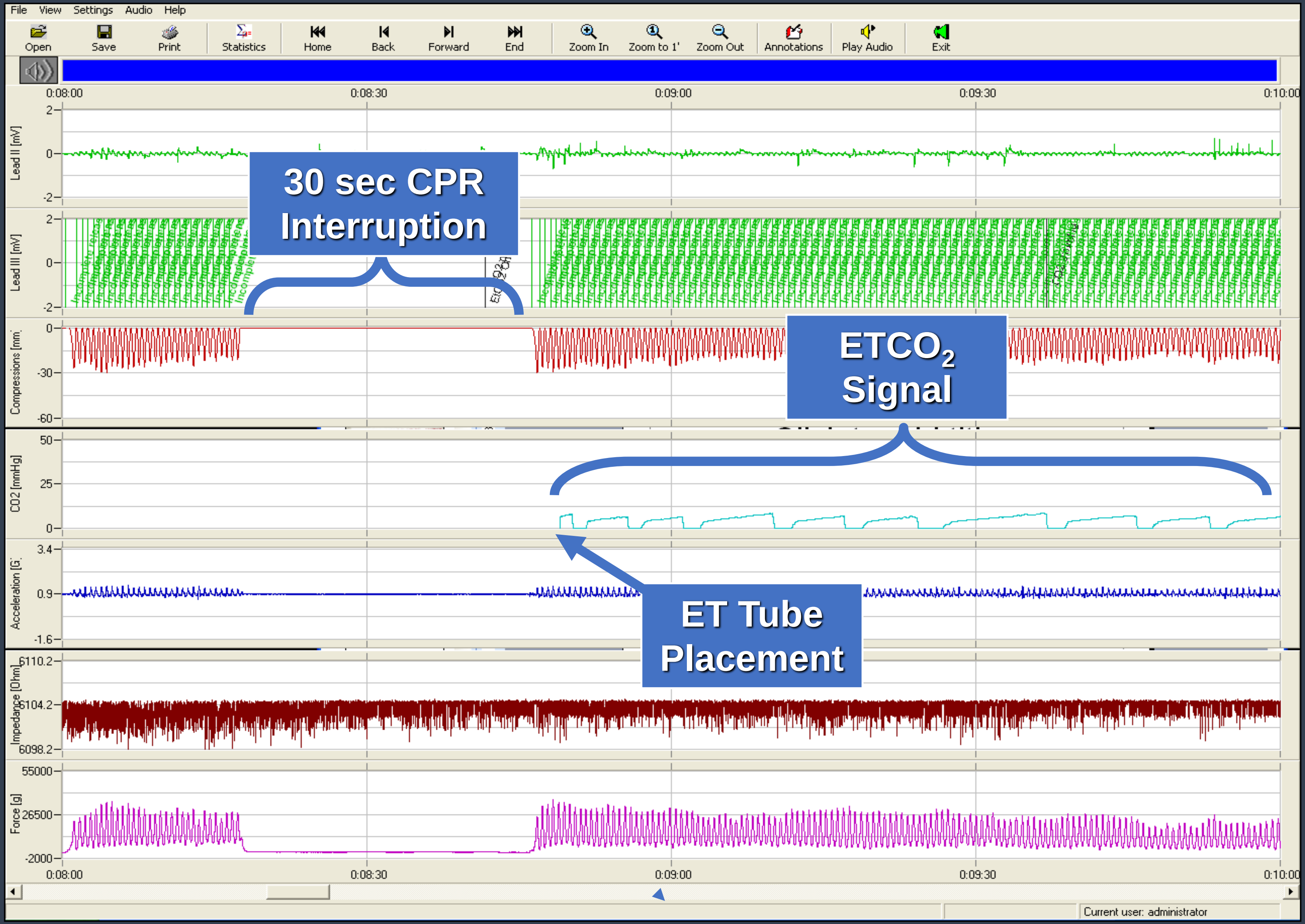
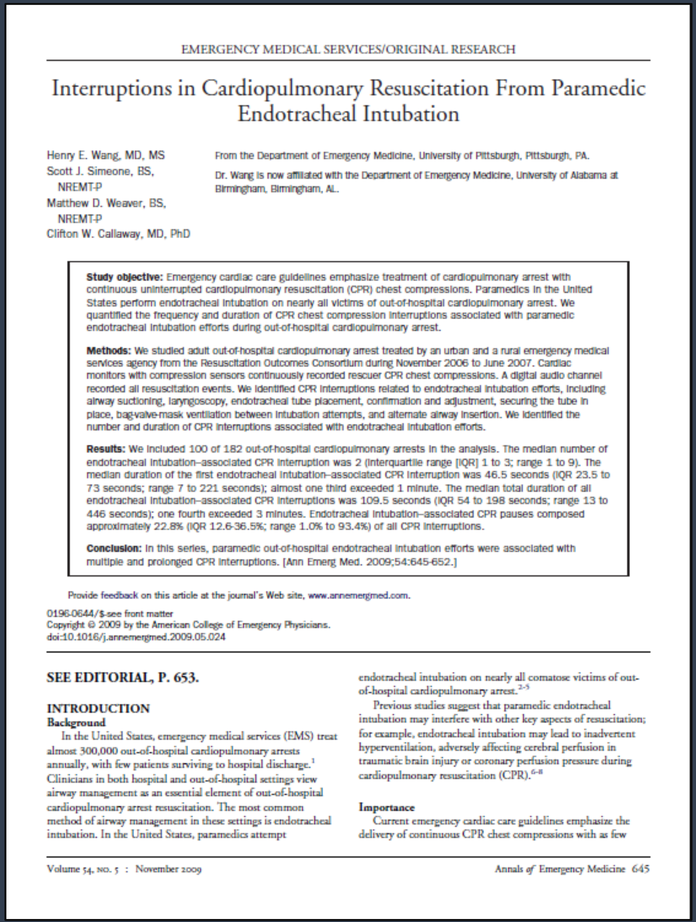


Intubation-Associated Chest Compression Interruptions

- Wang, Annals EM 2009
- Pittsburgh
- N=100
- Review of CPR process files and audio recordings
- Identified all CPR interruptions due to intubation efforts



EMERGENCY MEDICAL SERVICES/ORIGINAL RESEARCH

Interruptions in Cardiopulmonary Resuscitation From Paramedic Endotracheal Intubation

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Study objective: Emergency cardiac care guidelines emphasize treatment of cardiopulmonary arrest with continuous uninterrupted cardiopulmonary resuscitation (CPR) chest compressions. Paramedics in the United States perform endotracheal intubation on nearly all victims of out-of-hospital cardiopulmonary arrest. We quantified the frequency and duration of CPR chest compression interruptions associated with paramedic endotracheal intubation efforts during out-of-hospital cardiopulmonary arrest.

Methods: We studied adult out-of-hospital cardiopulmonary arrest treated by an urban and a rural emergency medical services agency from the Resuscitation Outcomes Consortium during November 2006 to June 2007. Cardiac monitors with compression sensors continuously recorded rescuer CPR chest compressions. A digital audio channel recorded all resuscitation events. We identified CPR interruptions related to endotracheal intubation efforts, including airway suctioning, laryngoscopy, endotracheal tube placement, confirmation and adjustment, securing the tube in place, bag-valve-mask ventilation between intubation attempts, and alternate airway insertion. We identified the number and duration of CPR interruptions associated with endotracheal intubation efforts.

Results: We included 100 of 182 out-of-hospital cardiopulmonary arrests in the analysis. The median number of endotracheal intubation–associated CPR interruption was 2 (interquartile range [IQR] 1 to 3; range 1 to 9). The median duration of the first endotracheal intubation–associated CPR interruption was 46.5 seconds (IQR 23.5 to 73 seconds; range 7 to 221 seconds); almost one third exceeded 1 minute. The median total duration of all endotracheal intubation–associated CPR interruptions was 109.5 seconds (IQR 54 to 198 seconds; range 13 to 446 seconds); one fourth exceeded 3 minutes. Endotracheal intubation–associated CPR pauses composed approximately 22.8% (IQR 12.6-36.5%; range 1.0% to 93.4%) of all CPR interruptions.

Conclusion: In this series, paramedic out-of-hospital endotracheal intubation efforts were associated with multiple and prolonged CPR interruptions. [Ann Emerg Med. 2009;54:645-652.]

Provide feedback on this article at the journal's Web site, www.annemergmed.com.

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2009.05.024

SEE EDITORIAL, P. 653.

INTRODUCTION

Background

In the United States, emergency medical services (EMS) treat almost 300,000 out-of-hospital cardiopulmonary arrests annually, with few patients surviving to hospital discharge.[1] Clinicians in both hospital and out-of-hospital settings view airway management as an essential element of out-of-hospital cardiopulmonary arrest resuscitation. The most common method of airway management in these settings is endotracheal intubation. In the United States, paramedics attempt endotracheal intubation on nearly all comatose victims of out-of-hospital cardiopulmonary arrest.[2-5]

Previous studies suggest that paramedic endotracheal intubation may interfere with other key aspects of resuscitation; for example, endotracheal intubation may lead to inadvertent hyperventilation, adversely affecting cerebral perfusion in traumatic brain injury or coronary perfusion pressure during cardiopulmonary resuscitation (CPR).[6-8]

Importance

Current emergency cardiac care guidelines emphasize the delivery of continuous CPR chest compressions with as few

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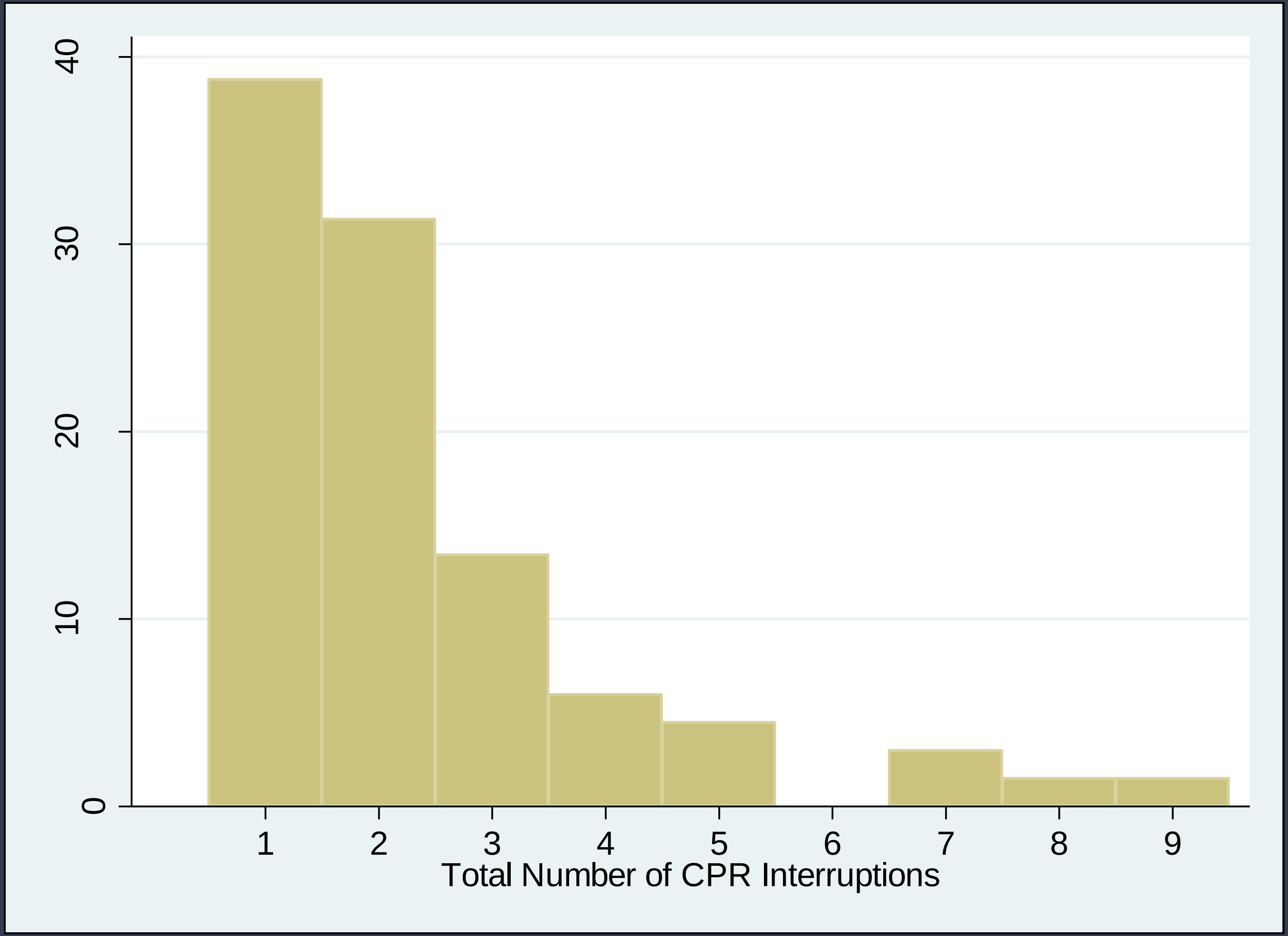
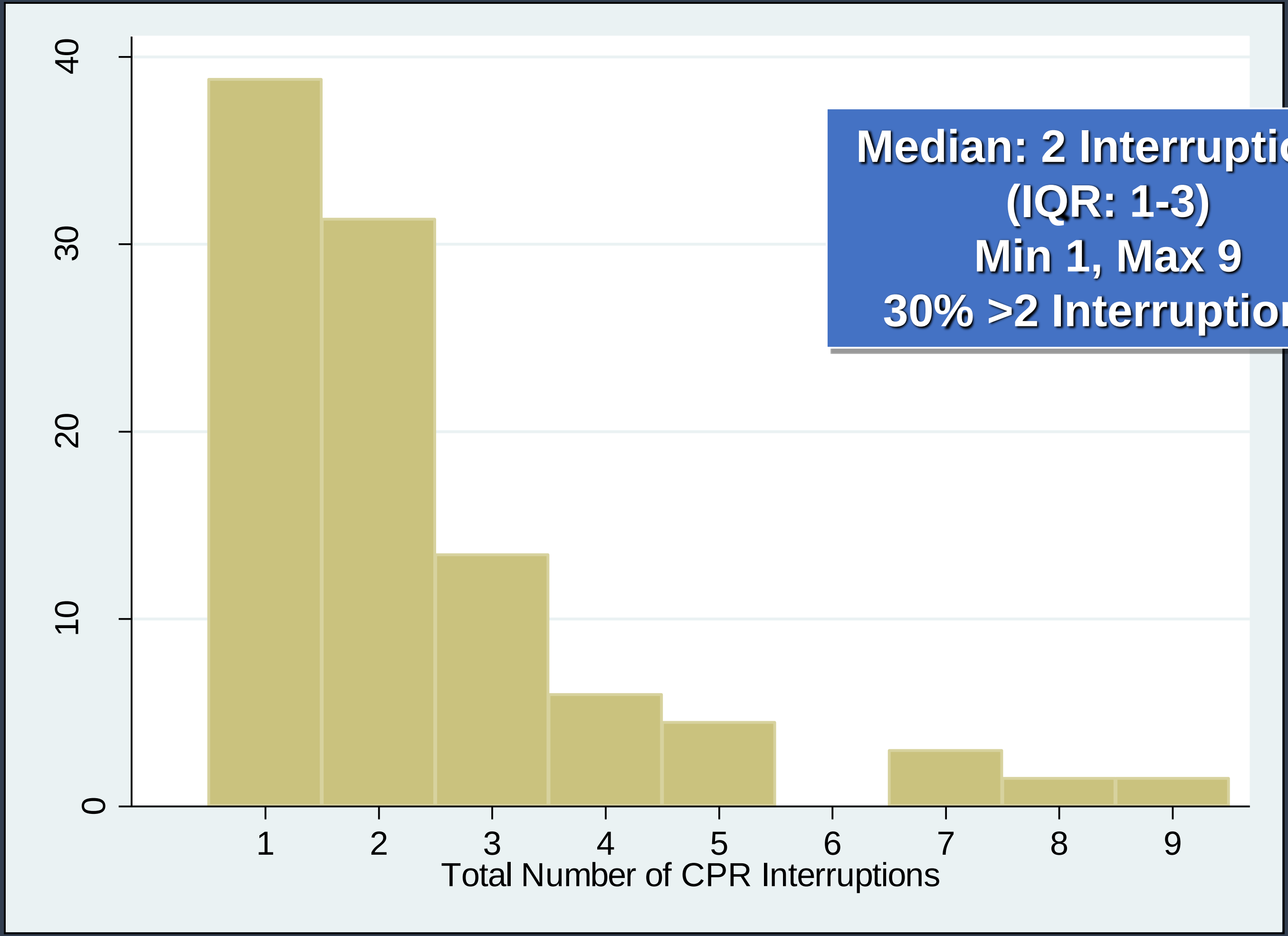
Intubation-Associated CPR Interruptions



Pittsburgh, n=100

Wang, et al., Ann Emerg Med 2009

Intubation-Associated CPR Interruptions

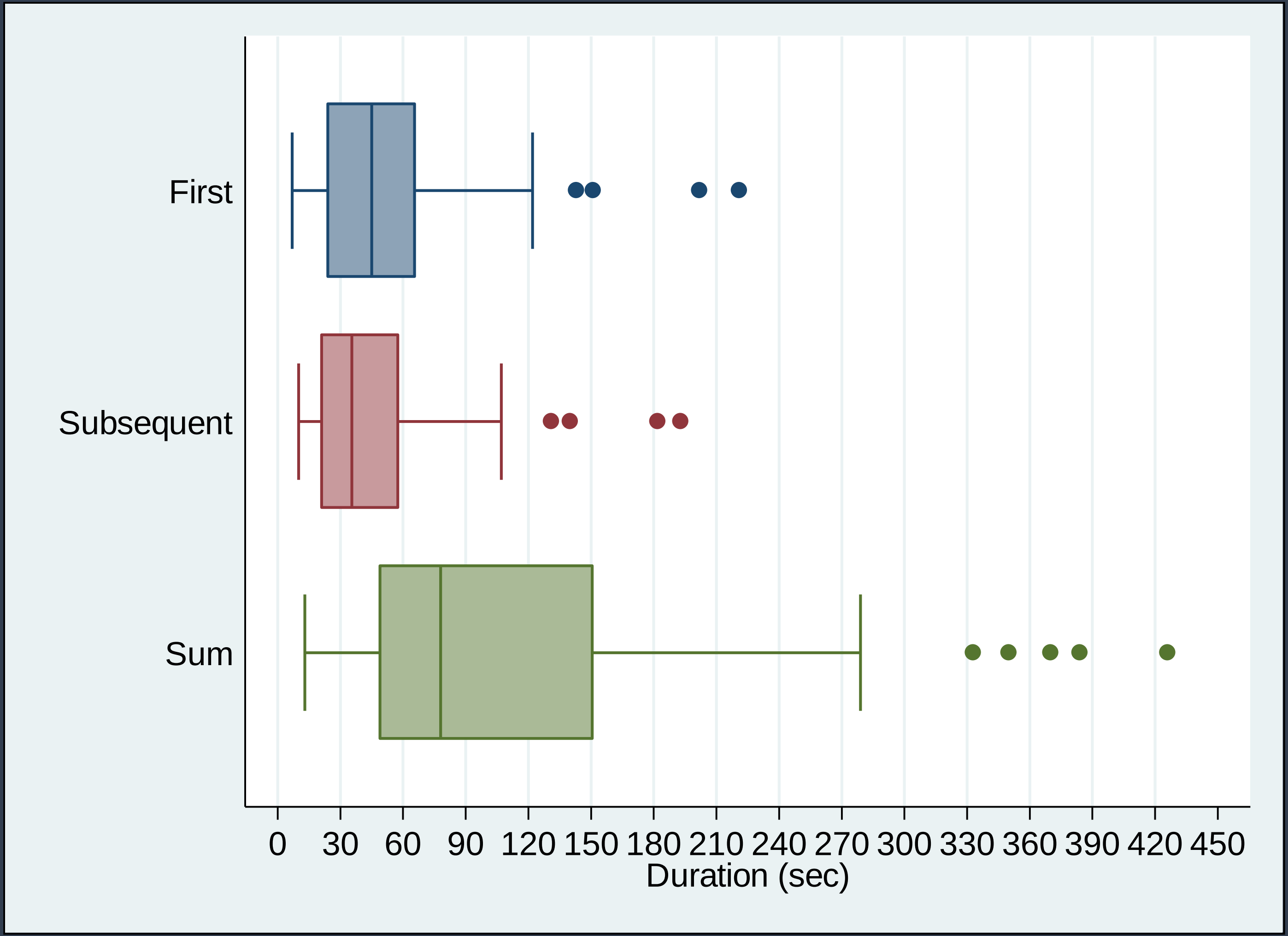


Median: 2 Interruptions
(IQR: 1-3)
Min 1, Max 9
30% >2 Interruptions

Pittsburgh, n=100

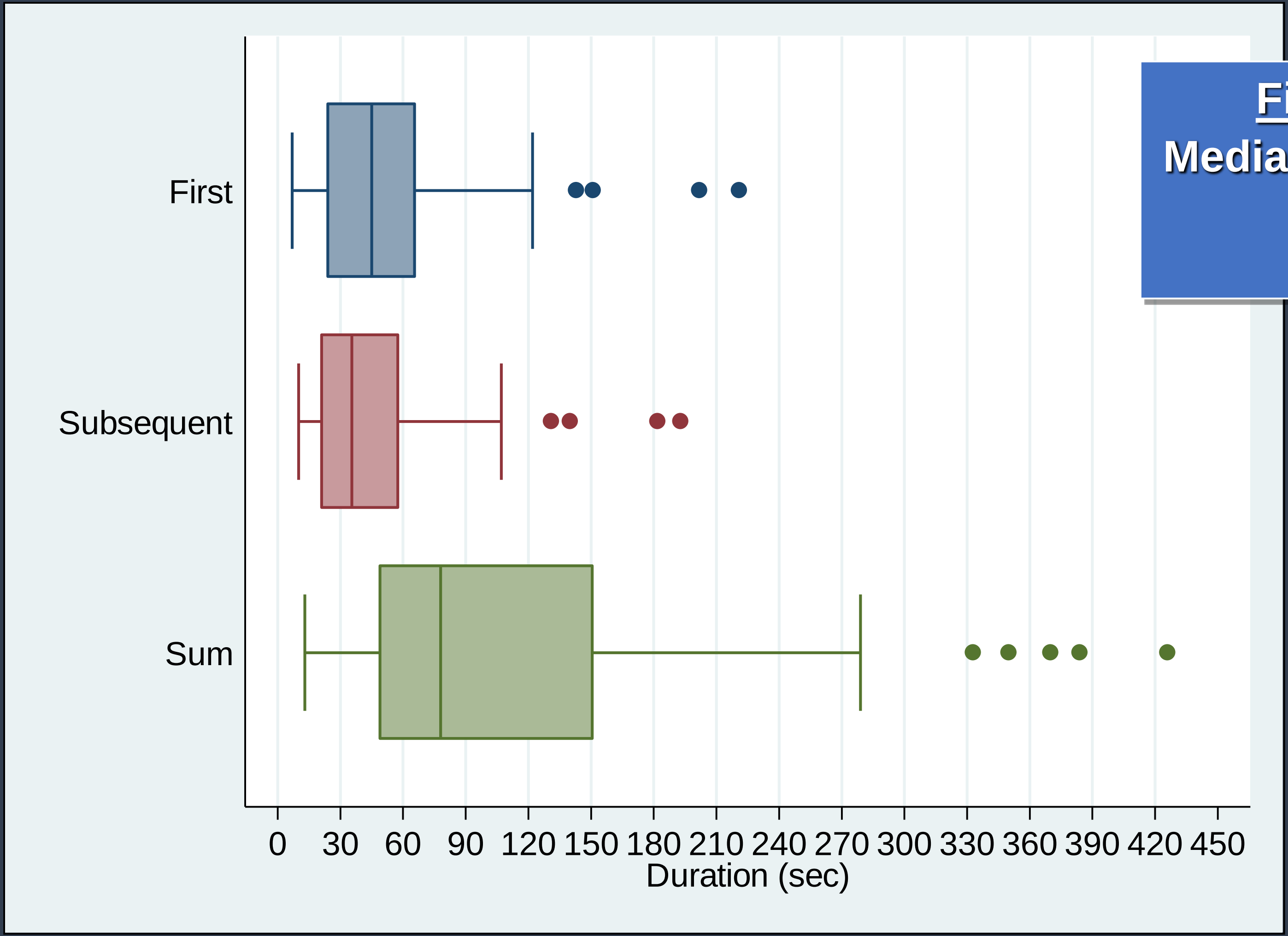
Wang, et al., Ann Emerg Med 2009

Duration of Intubation-Associated CPR Interruptions



Wang, et al., Ann Emerg Med 2009

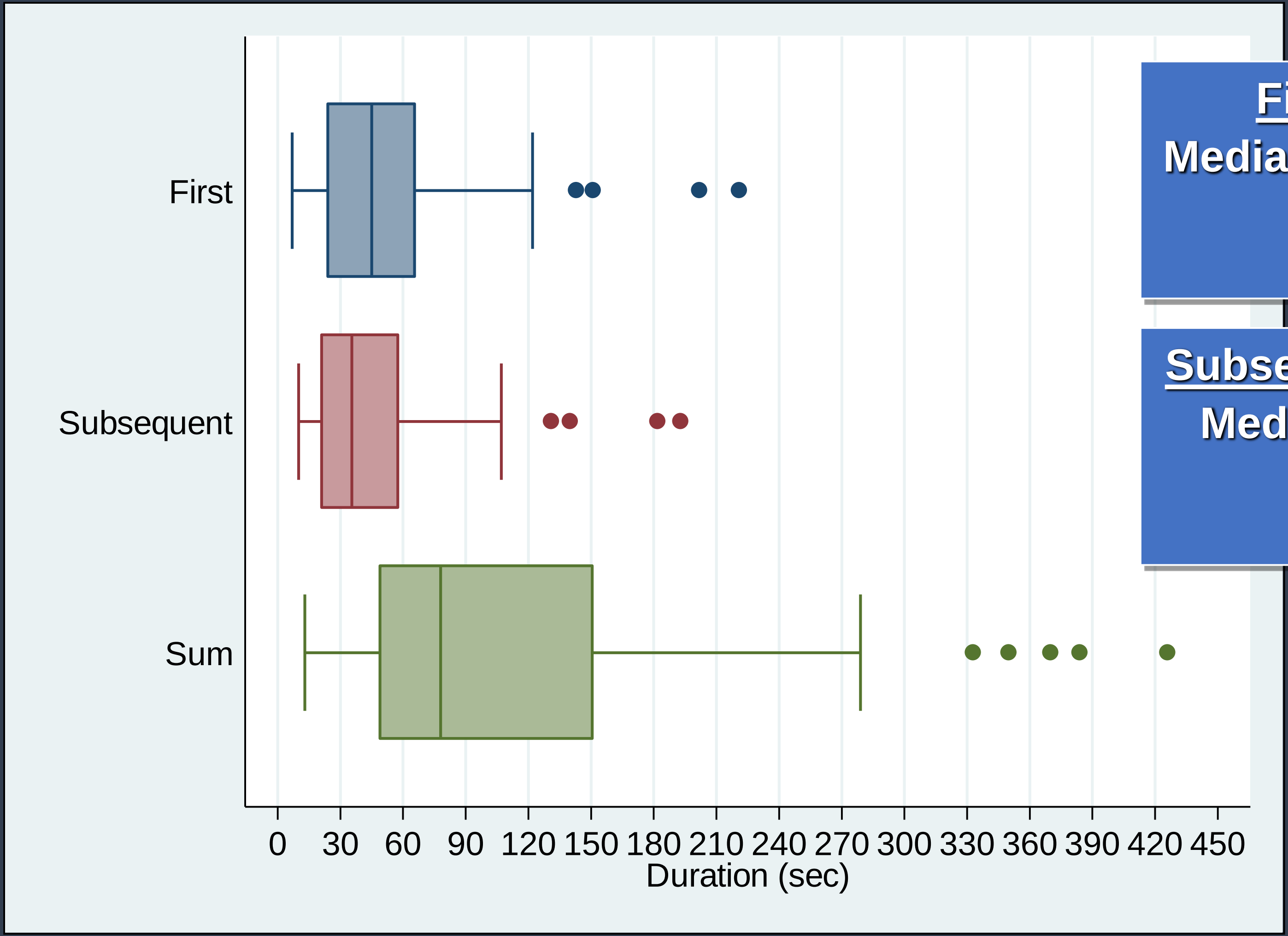
Duration of Intubation-Associated CPR Interruptions



First CPR Interruption
Median: 46.5 sec (IQR: 23.5-73)
Min 7, Max 221
~30% >60 sec

Wang, et al., Ann Emerg Med 2009

Duration of Intubation-Associated CPR Interruptions



First CPR Interruption

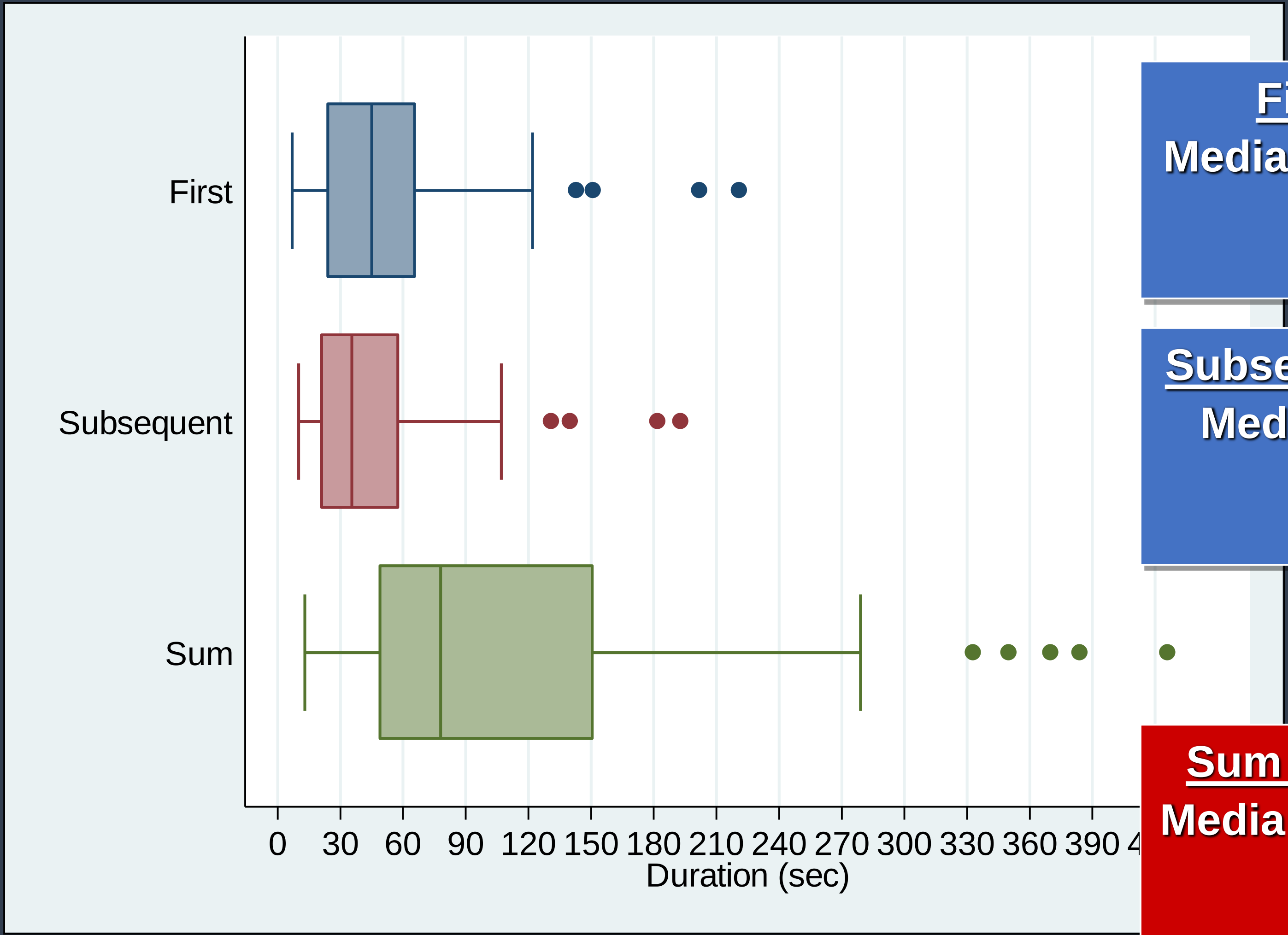
Median: 46.5 sec (IQR: 23.5-73)
Min 7, Max 221
~30% >60 sec

Subsequent CPR Interruptions

Median: 35 sec (IQR: 21-58)
Min 7, Max 199
~20% >60 sec

Wang, et al., Ann Emerg Med 2009

Duration of Intubation-Associated CPR Interruptions



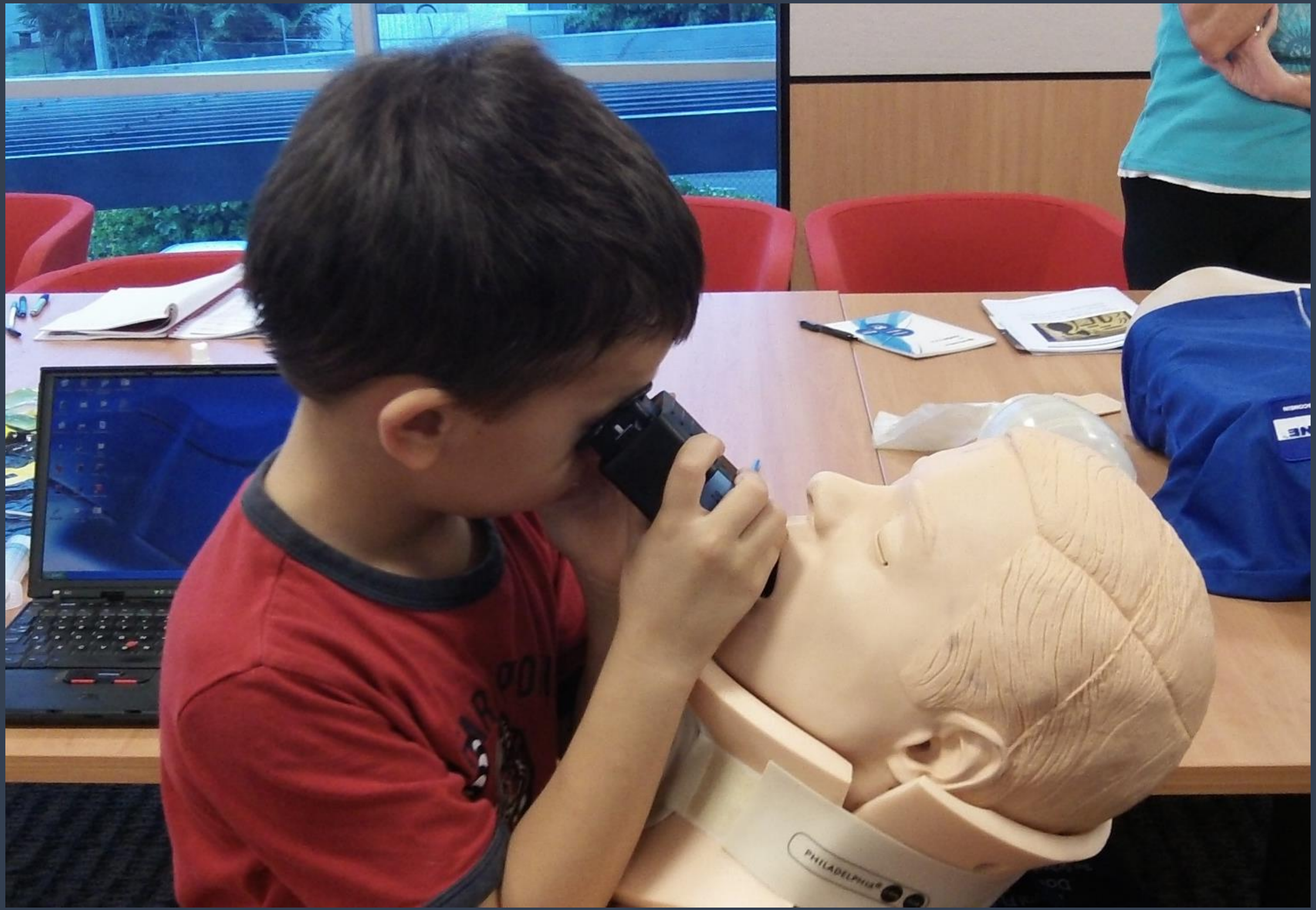
<u>First CPR Interruption</u>
Median: 46.5 sec (IQR: 23.5-73)
Min 7, Max 221
~30% >60 sec

<u>Subsequent CPR Interruptions</u>
Median: 35 sec (IQR: 21-58)
Min 7, Max 199
~20% >60 sec

<u>Sum of All CPR Interruptions</u>
Median: 109.5 sec (IQR: 54-198)
Min 13, Max 446
~25% >180 sec

Wang, et al., Ann Emerg Med 2009

“Does Training Play a Role?”



Intubation is Difficult in Prehospital Mosh Pit

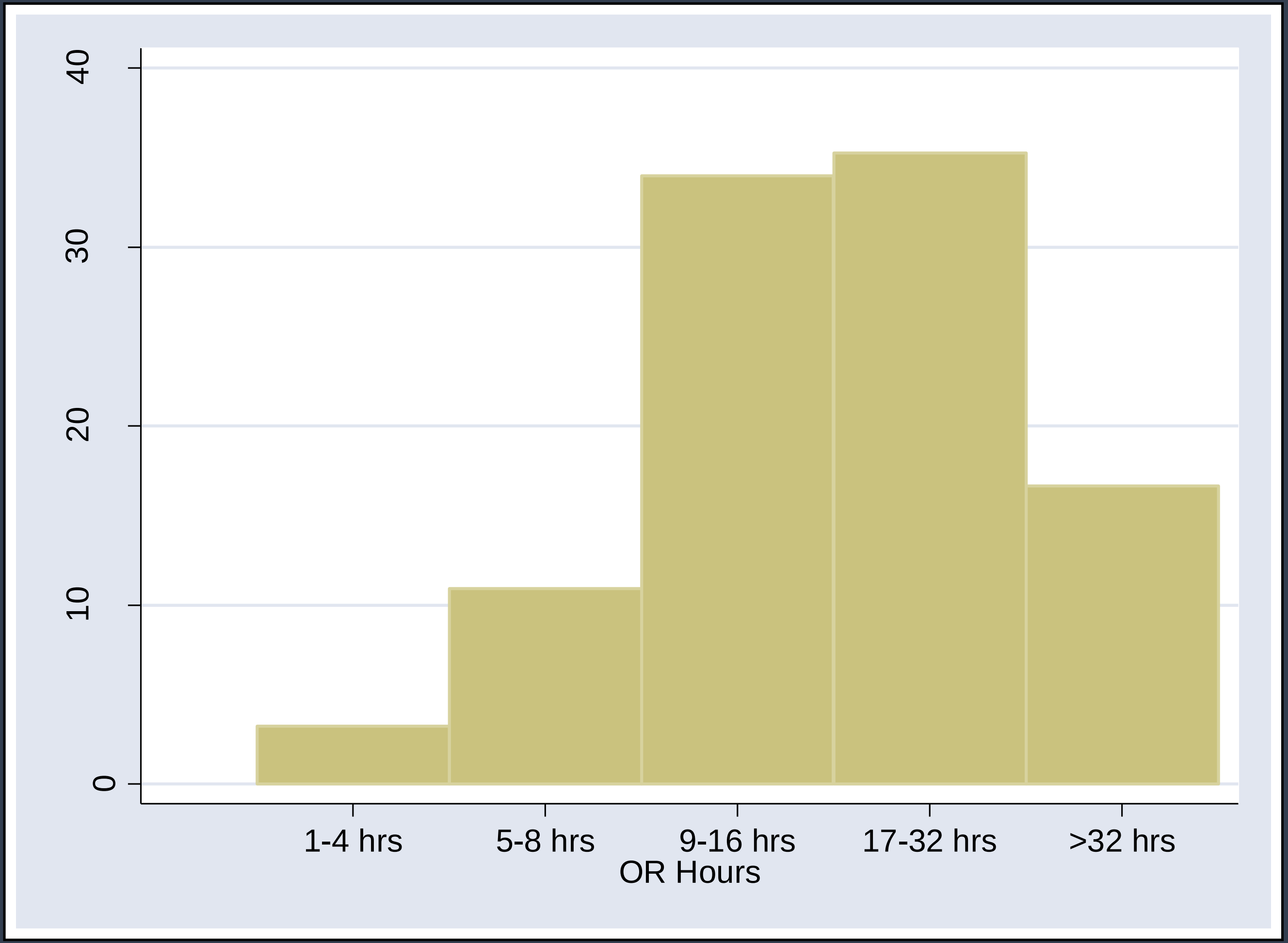
“There’s no such thing as an easy prehospital airway”

“Paramedics need exceptional intubation skills”

How Many Intubations
Do You Need to Graduate in the US?

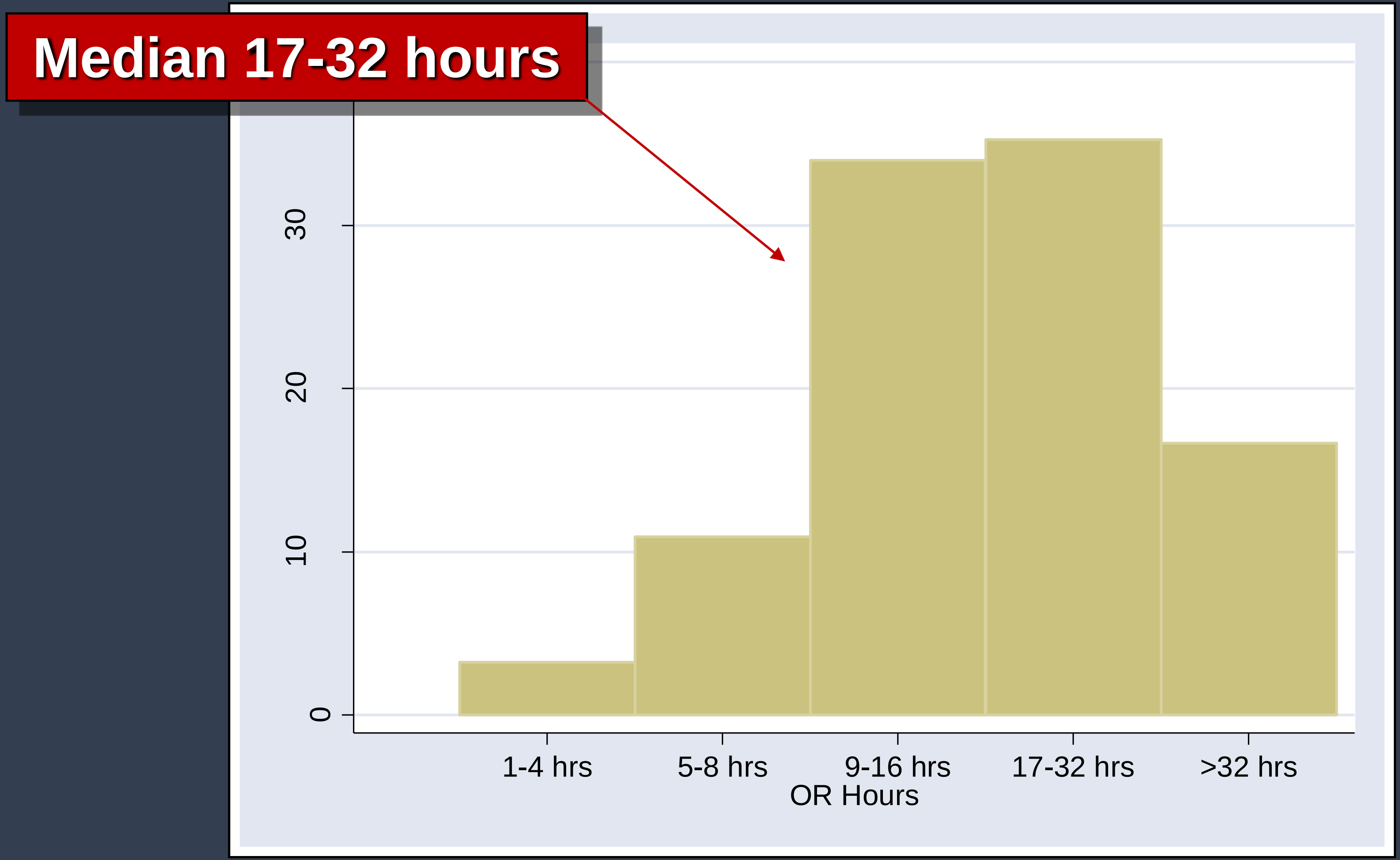
- **Emergency Med Residents** **35**
- **Anesthesia Residents** **20-57**
- **CRNA Students** **200**
- **Paramedic Students** **5**

Paramedic Student
Operating Room Training Hours



Johnston, et al., Acad Emerg Med 2006

Paramedic Student
Operating Room Training Hours



Johnston, et al., Acad Emerg Med 2006

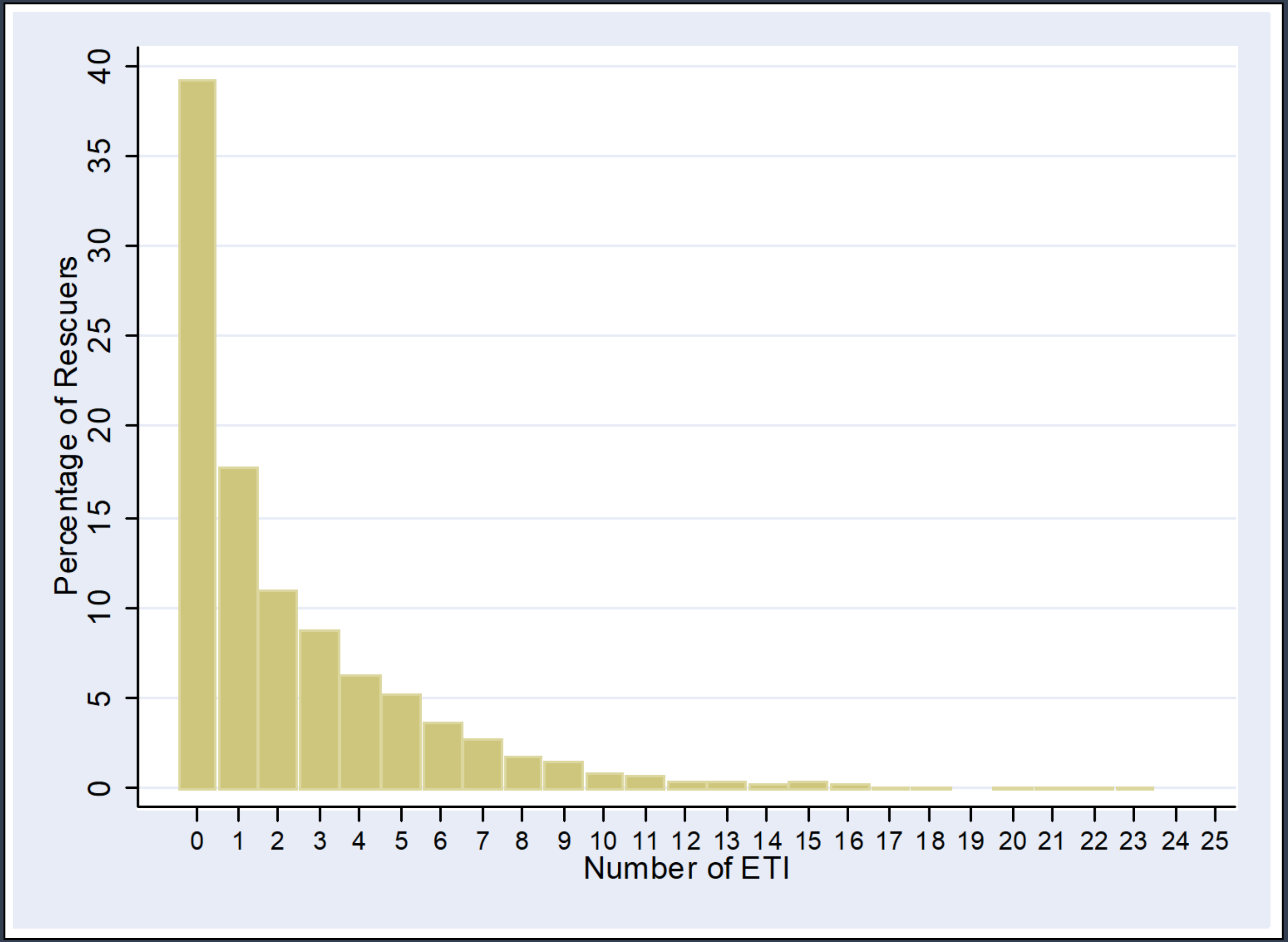
Paramedic Student Operating Room Barriers

- Competition from other students
- Widespread Laryngeal Mask Airway use
- Anesthesiologists' medicolegal concerns

Intubation Skill

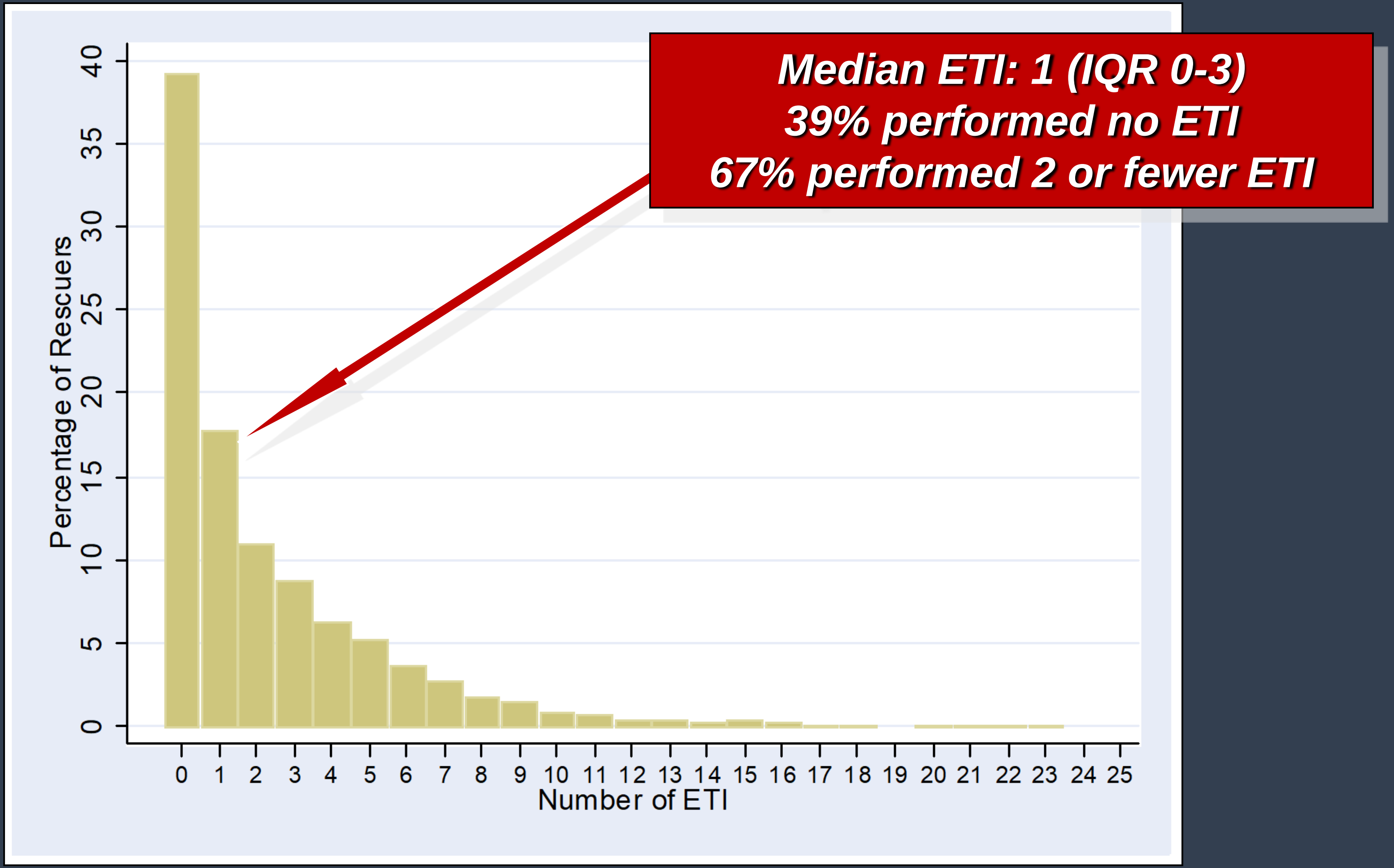
“Skill” (“Proficiency”)	=	Baseline Training	+	Regular Application

Intubations Per Paramedic
Pennsylvania 2003



Wang, et al. Crit Care Med 2005

Intubations Per Paramedic
Pennsylvania 2003



Wang, et al. Crit Care Med 2005

“We Have a Problem . . .”

- Prehospital ETI clinical benefit not proven
- Prone to error
- Difficult
- Interacts with other interventions
- Performed under worst possible conditions
- Limited training

"There is an Alternative…"

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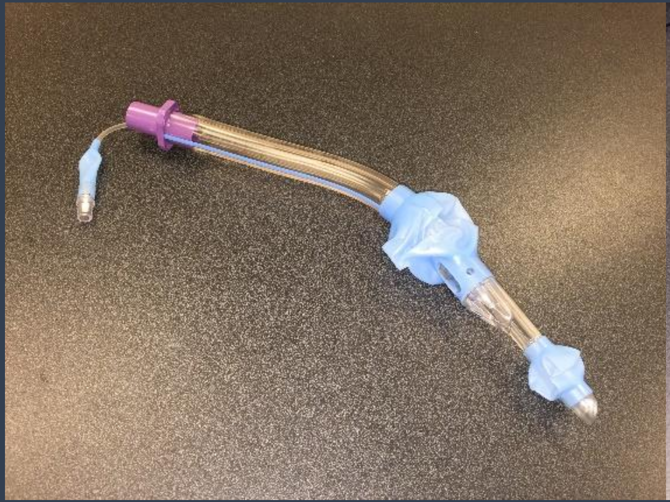
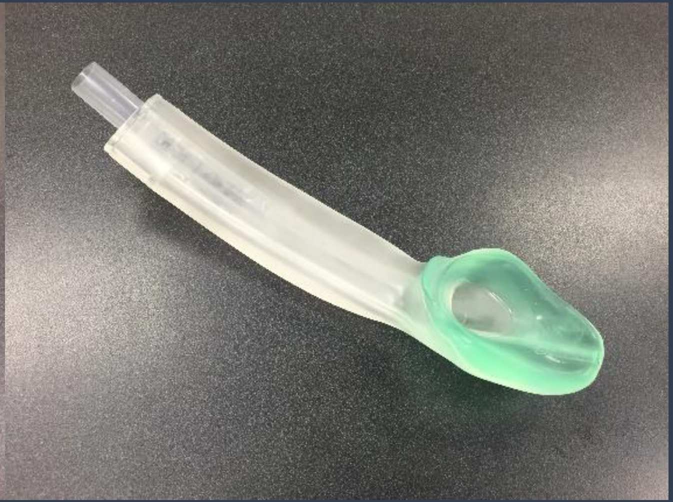
Supraglottic Airways (SGA)

- Easier technique
- Less training required
- Similar ventilation to ETI
- Increasing use as primary airway in OHCA



King Laryngeal Tube (LT)

Laryngeal Mask Airway (LMA)



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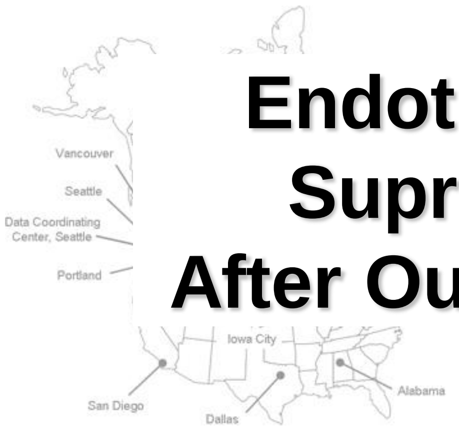
"SGA vs ETI – Unexpected Results"

Resuscitation Outcomes Consortium



Endotracheal Intubation Versus Supraglottic Airway Insertion After Out-of-Hospital Cardiac Arrest

Henry E. Wang, MD, MS

Department of Emergency Medicine, University of Alabama at Birmingham

Danny Syzdlo, MS; John Stouffer, EMT-P; Steve Lin, MDCM; Jestin Carlson, MD; Christian Vaillancourt, MD; Gena Sears, BSN; Richard Verbeek, MD; Raymond Fowler, MD; Ahamed Idris, MD; Karl Koenig, EMT-P; James Christenson, MD; Anush Minokadeh, MD; Joseph Brandt, EMT-P; Thomas Rea, MD; and the ROC Investigators

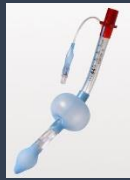
ETI vs. SGA in Cardiac Arrest
ROC PRIMED Trial

10,455 OHCA

8,457 ETI

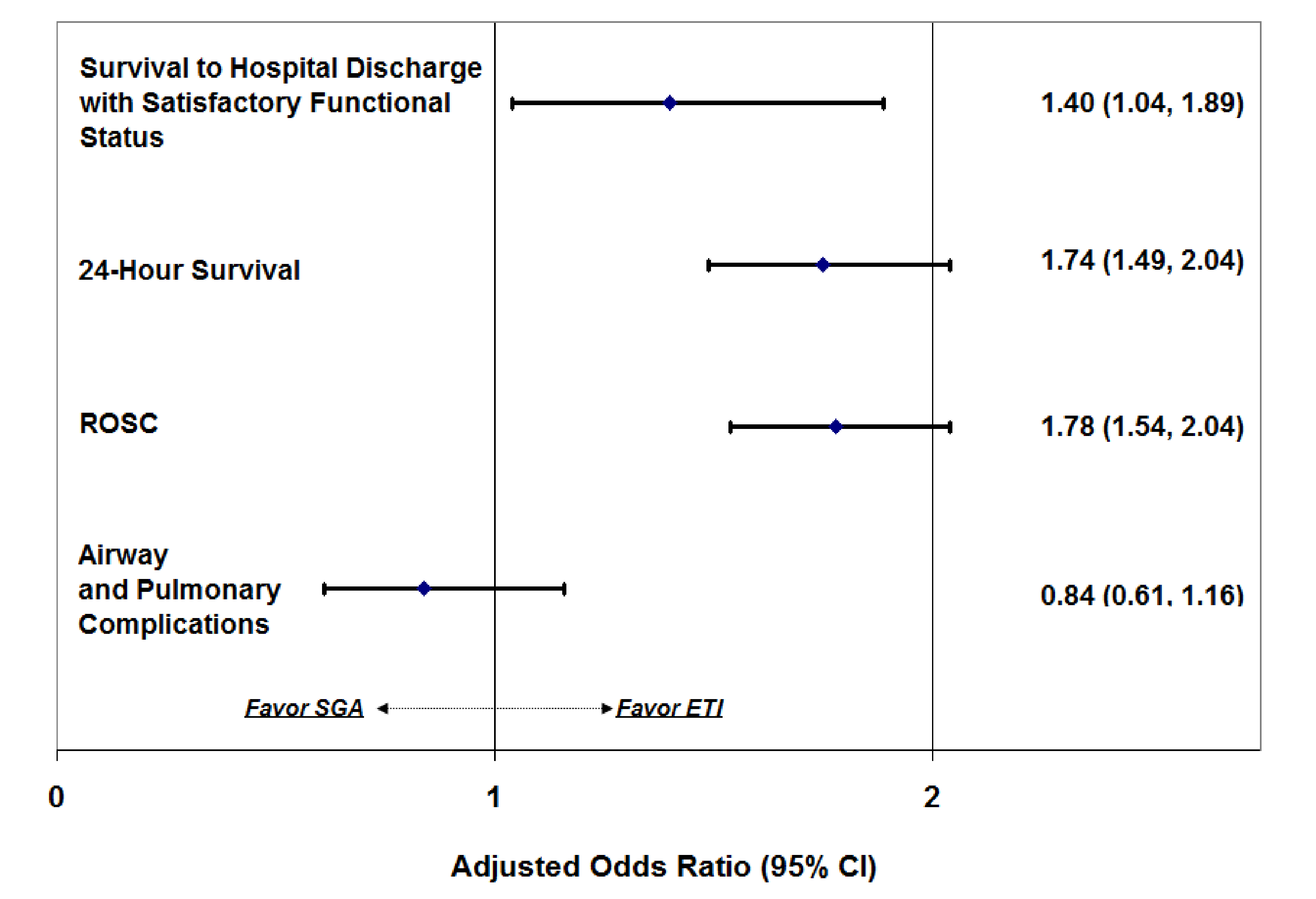
1,968 SGA

- **909 King**
- **296 Combitube**
- **239 LMA**
- **518 Unknown**



RESUSCITATION OUTCOMES CONSORTIUM

ETI Wins over SGA (Oops…)



Wang, Resuscitation 2012

RESUSCITATION OUTCOMES CONSORTIUM

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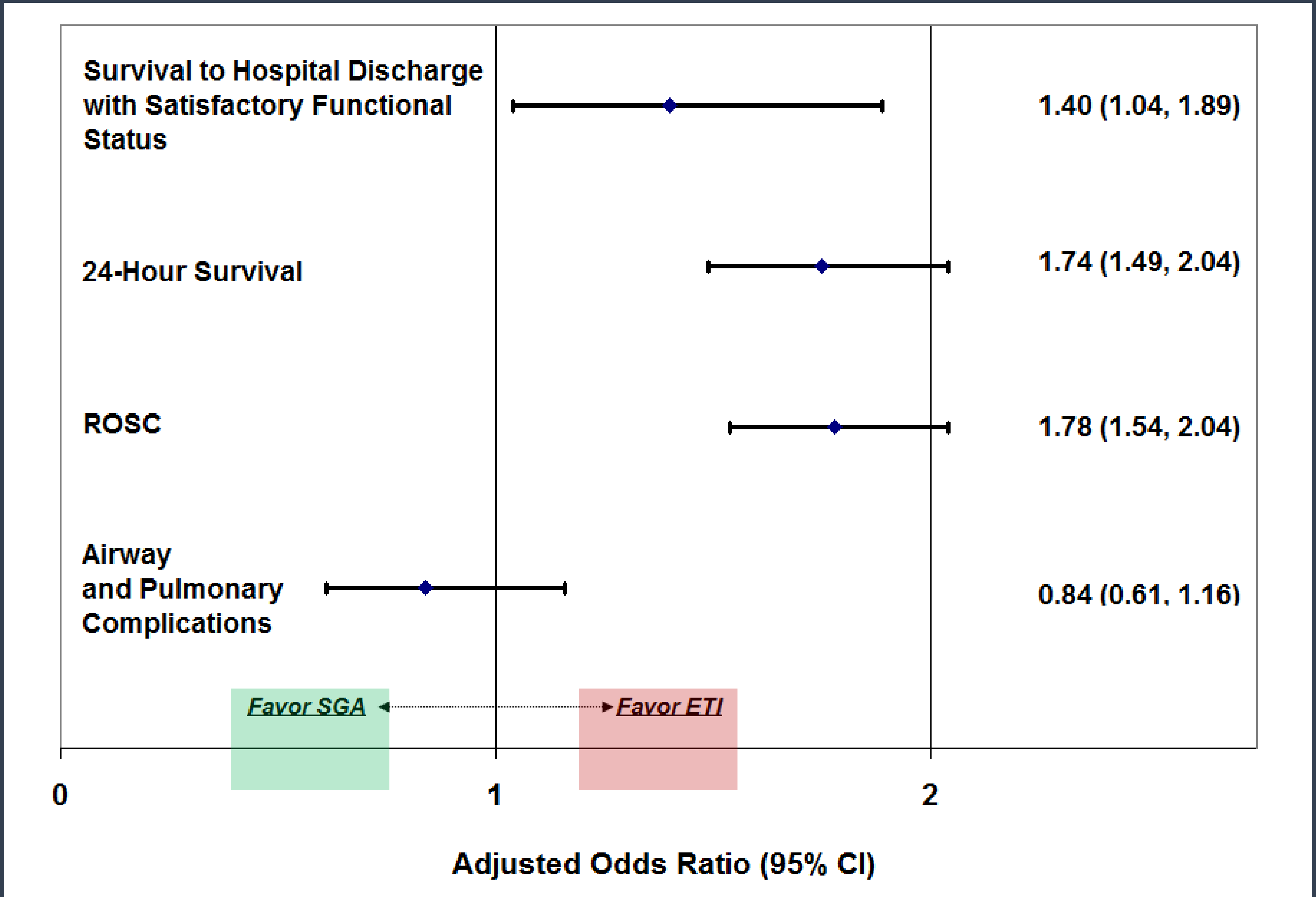

Wang, Resuscitation 2012

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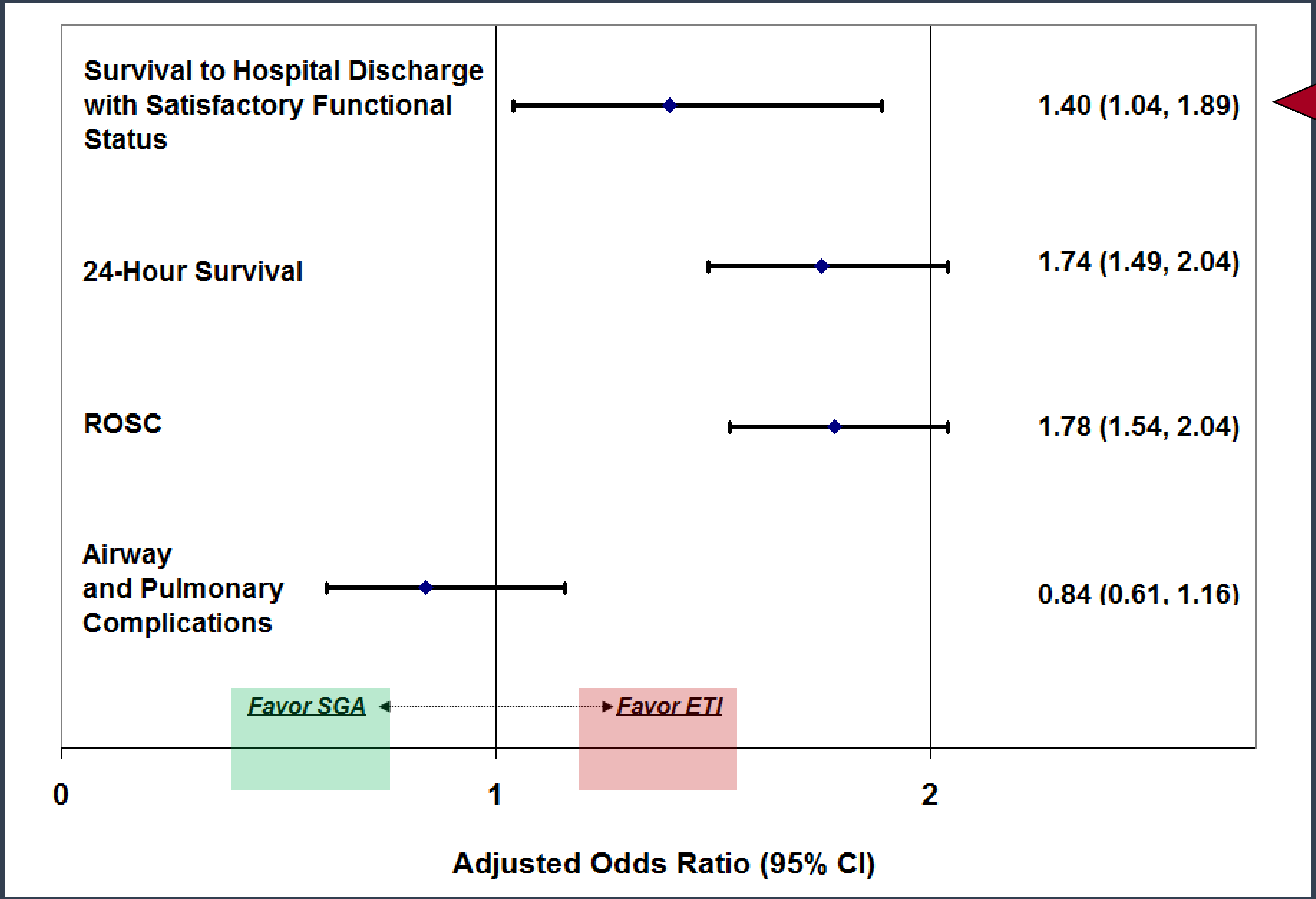

Wang, Resuscitation 2012

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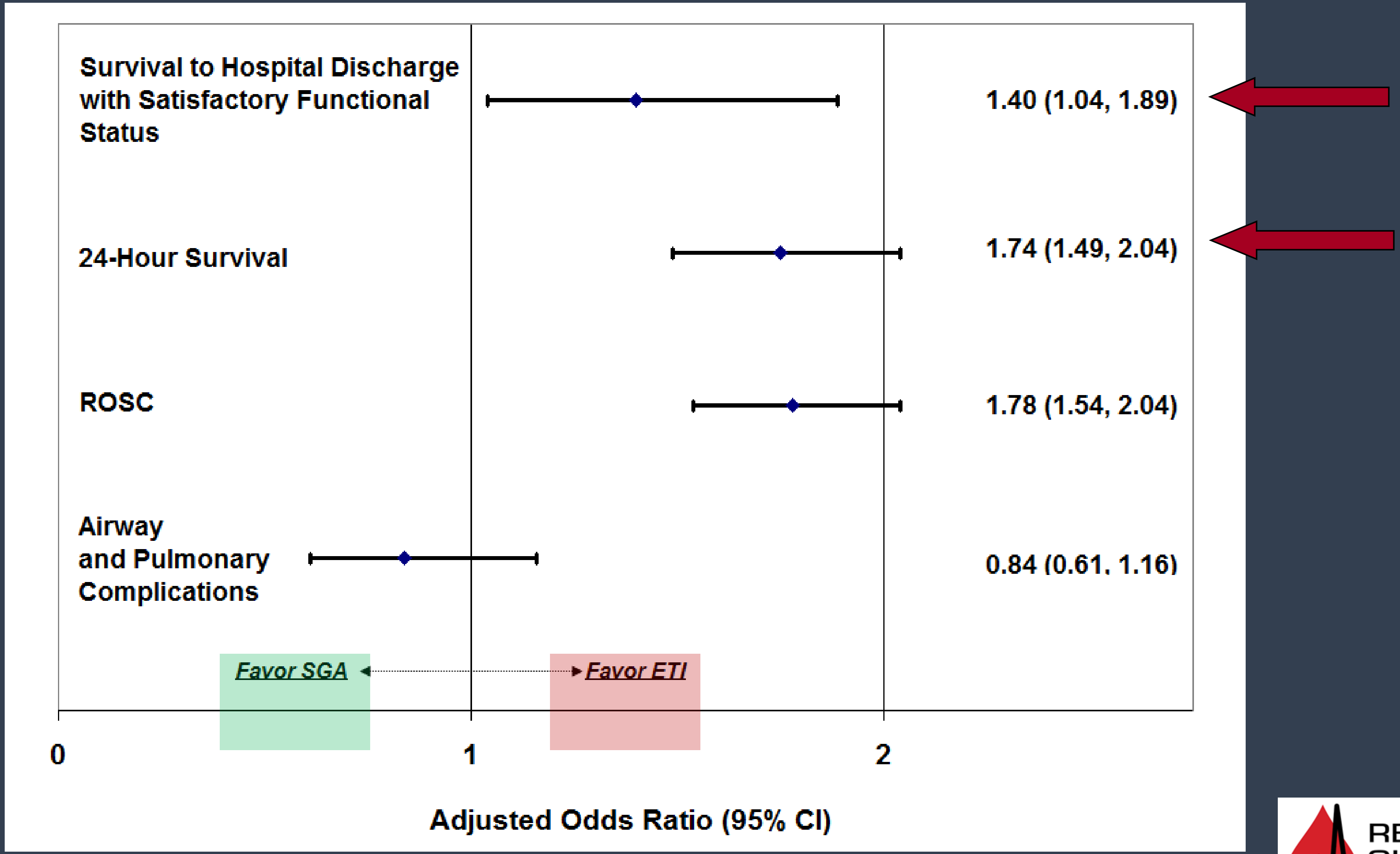
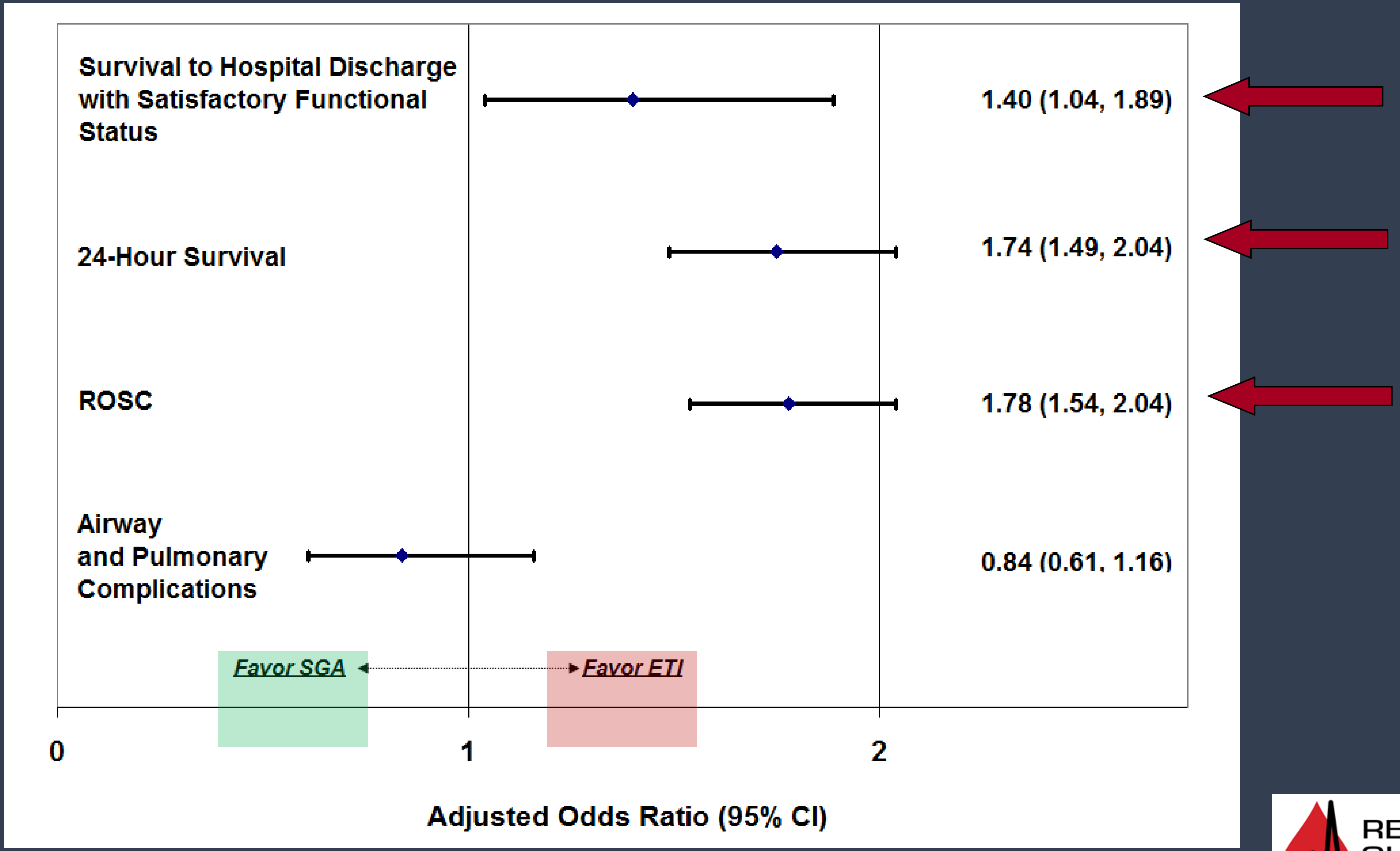


Wang, Resuscitation 2012

RESUSCITATION OUTCOMES CONSORTIUM

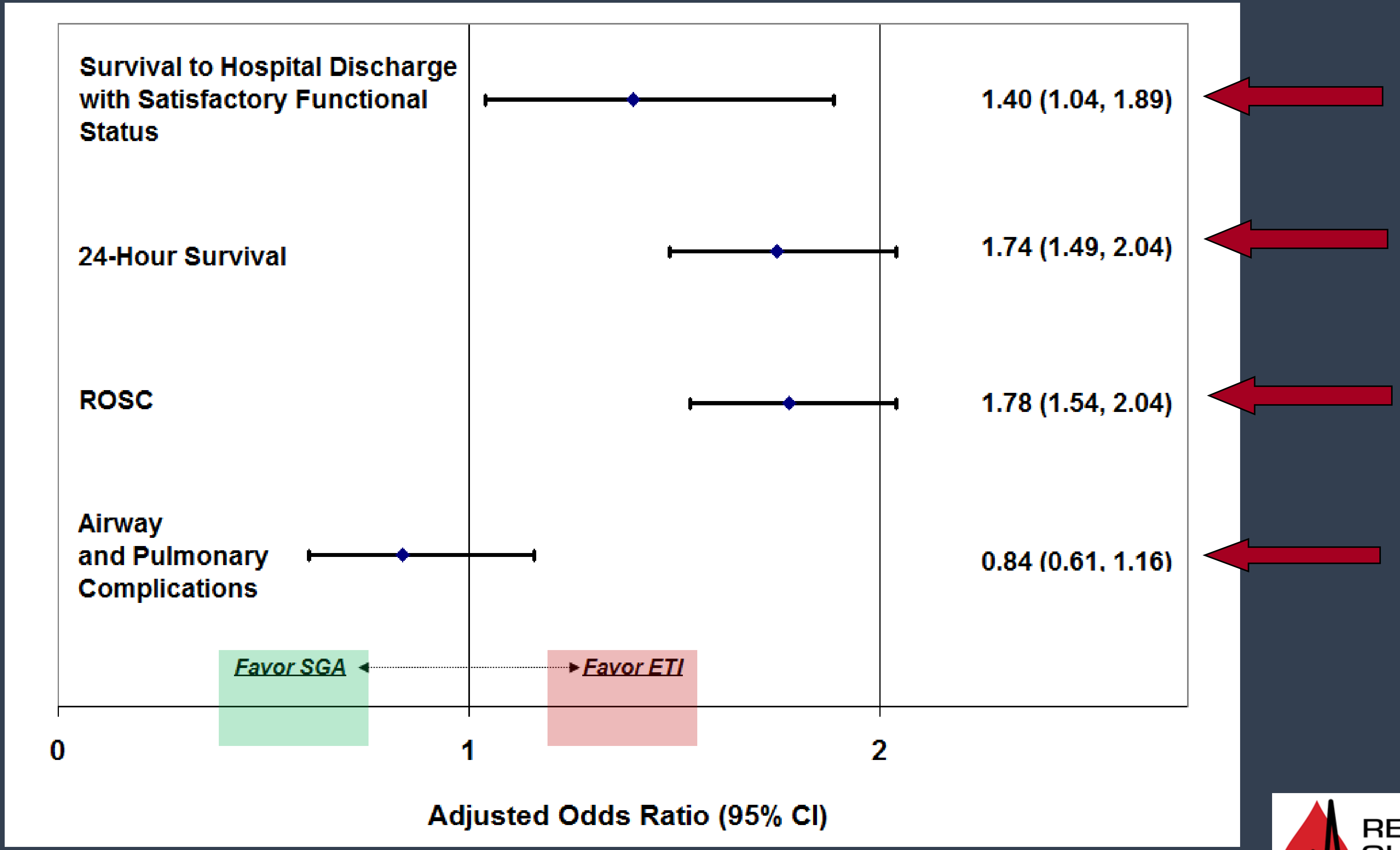
ETI Wins over SGA (Oops…)



RESUSCITATION OUTCOMES CONSORTIUM

Wang, Resuscitation 2012

ETI Wins over SGA (Oops…)

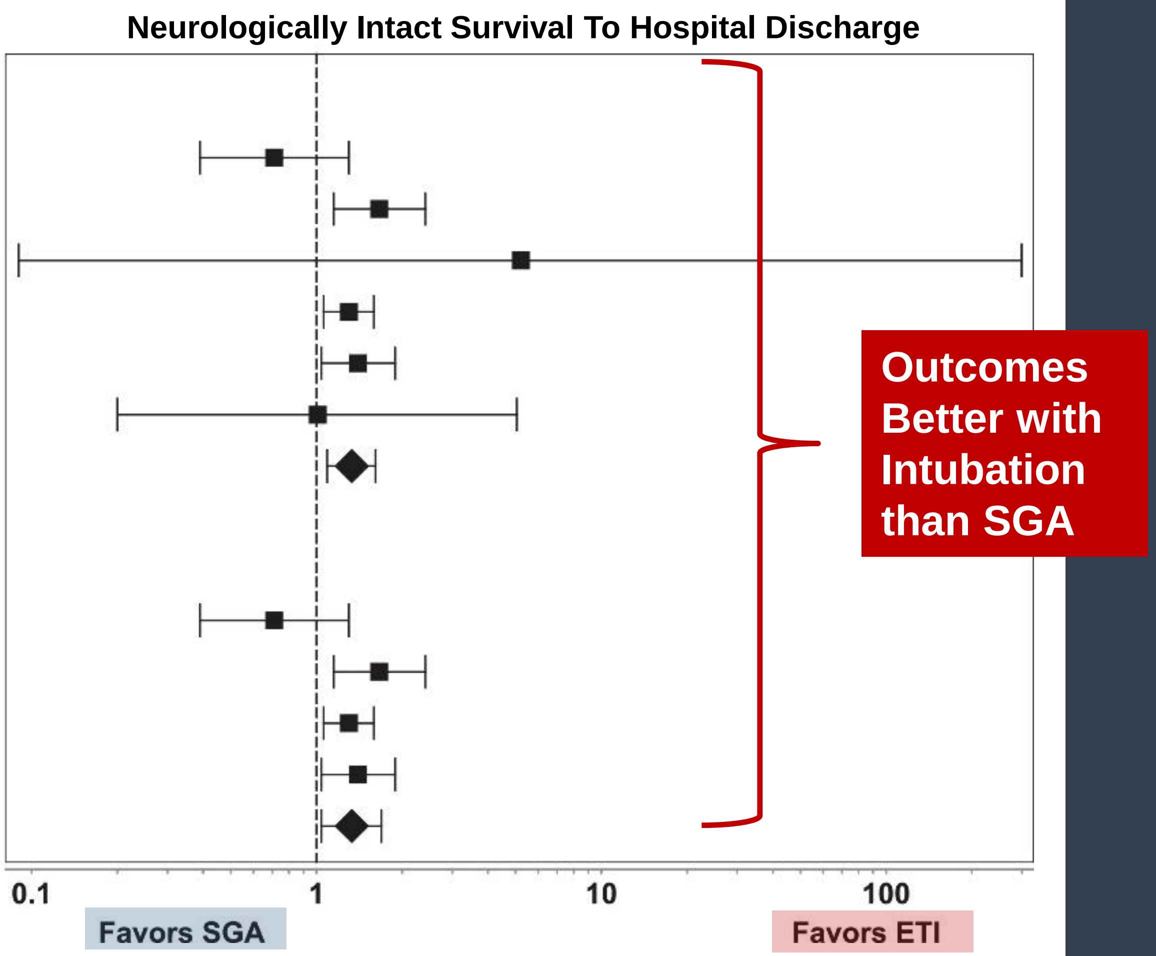


Wang, Resuscitation 2012

RESUSCITATION OUTCOMES CONSORTIUM

ETI vs. SGA
Meta Analysis of Observational Studies

Study	N (ETI)	N (SGA)	OR (95% CI)
FULL MODEL:			
Kajino 2011	1679	3698	0.71 (0.39-1.30)
McMullan 2014	5591	3110	1.66 (1.15-2.41)
Noda 2007	4	24	5.22 (0.09-299.04)
Tanabe 2013	12992	29640	1.30 (1.06-1.59)
Wang 2012	8487	1968	1.40 (1.04-1.89)
Yanagawa 2010	158	478	1.01 (0.20-5.05)
TOTAL	28911	38918	1.33 (1.09-1.61)
SENSITIVITY ANALYSIS MODEL:			
Kajino 2011	1679	3698	0.71 (0.39-1.30)
McMullan 2014	5591	3110	1.66 (1.15-2.41)
Tanabe 2013	12992	29640	1.30 (1.06-1.59)
Wang 2012	8487	1968	1.40 (1.04-1.89)
TOTAL	28749	38416	1.33 (1.04-1.69)



Benoit, Resuscitation, 2015

A Randomized Trial is Necessary

- Confounding-by-indication

- Randomization is only way to overcome confounding-by-indication

"Three Landmark Airway Management Clinical Trials"

Pragmatic Airway Resuscitation Trial (PART)

Wang, et al, JAMA 2018

JAMA | Original Investigation

Effect of a Strategy of Initial Laryngeal Tube Insertion vs Endotracheal Intubation on 72-Hour Survival in Adults With Out-of-Hospital Cardiac Arrest
A Randomized Clinical Trial

Henry E. Wang, MD, MS; Robert H. Schmicker, MS; Mohamud R. Daya, MD, MS; Shannon W. Stephens, EMT-P; Ahamed H. Idris, MD; Jestin N. Carlson, MD, MS; M. Riccardo Colella, DO, MPH; Heather Herren, MPH, RN; Matthew Hansen, MD, MCR; Neal J. Richmond, MD; Juan Carlos J. Puyana, BA; Tom P. Aufderheide, MD, MS; Randal E. Gray, MEd, NREMT-P; Pamela C. Gray, NREMT-P; Mike Verkest, AAS, EMT-P; Pamela C. Owens; Ashley M. Brienza, BS; Kenneth J. Sternig, MS-EHS, BSN, NRP; Susanne J. May, PhD; George R. Sopko, MD, MPH; Myron L. Weisfeldt, MD; Graham Nichol, MD, MPH

IMPORTANCE Emergency medical services (EMS) commonly perform endotracheal intubation (ETI) or insertion of supraglottic airways, such as the laryngeal tube (LT), on patients with out-of-hospital cardiac arrest (OHCA). The optimal method for OHCA advanced airway management is unknown.

OBJECTIVE To compare the effectiveness of a strategy of initial LT insertion vs initial ETI in adults with OHCA.

DESIGN, SETTING, AND PARTICIPANTS Multicenter pragmatic cluster-crossover clinical trial involving EMS agencies from the Resuscitation Outcomes Consortium. The trial included 3004 adults with OHCA and anticipated need for advanced airway management who were enrolled from December 1, 2015, to November 4, 2017. The final date of follow-up was November 10, 2017.

INTERVENTIONS Twenty-seven EMS agencies were randomized in 13 clusters to initial airway management strategy with LT (n = 1505 patients) or ETI (n = 1499 patients), with crossover to the alternate strategy at 3- to 5-month intervals.

MAIN OUTCOMES AND MEASURES The primary outcome was 72-hour survival. Secondary outcomes included return of spontaneous circulation, survival to hospital discharge, favorable neurological status at hospital discharge (Modified Rankin Scale score ≤3), and key adverse events.

RESULTS Among 3004 enrolled patients (median [interquartile range] age, 64 [53-76] years, 1829 [60.9%] men), 3000 were included in the primary analysis. Rates of initial airway success were 90.3% with LT and 51.6% with ETI. Seventy-two hour survival was 18.3% in the LT group vs 15.4% in the ETI group (adjusted difference, 2.9% [95% CI, 0.2%-5.6%]; *P* = .04). Secondary outcomes in the LT group vs ETI group were return of spontaneous circulation (27.9% vs 24.3%; adjusted difference, 3.6% [95% CI, 0.3%-6.8%]; *P* = .03); hospital survival (10.8% vs 8.1%; adjusted difference, 2.7% [95% CI, 0.6%-4.8%]; *P* = .01); and favorable neurological status at discharge (7.1% vs 5.0%; adjusted difference, 2.1% [95% CI, 0.3%-3.8%]; *P* = .02). There were no significant differences in oropharyngeal or hypopharyngeal injury (0.2% vs 0.3%), airway swelling (1.1% vs 1.0%), or pneumonia or pneumonitis (26.1% vs 22.3%).

CONCLUSIONS AND RELEVANCE Among adults with OHCA, a strategy of initial LT insertion was associated with significantly greater 72-hour survival compared with a strategy of initial ETI. These findings suggest that LT insertion may be considered as an initial airway management strategy in patients with OHCA, but limitations of the pragmatic design, practice setting, and ETI performance characteristics suggest that further research is warranted.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT02419573

JAMA. 2018;320(8):769-778. doi:10.1001/jama.2018.7044

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CME Quiz at jamanetwork.com/learning and CME Questions page 834

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PRAGMATIC AIRWAY RESUSCITATION TRIAL
ROC

Laryngeal Tube vs. Endotracheal Intubation in Adult Out-of-Hospital Cardiac Arrest

HE Wang, RH Schmicker, MR Daya, SW Stephens, AH Idris, JN Carlson, MR Colella, H Herren, M Hansen, NJ Richmond, JCJ Puyana, TP Aufderheide, RE Gray, PC Gray, M Verkest, PC Owens, AM Brienza, KJ Sternig, SJ May, GR Sopko, ML Weisfeldt, G Nichol

The University of Texas Health Science Center at Houston,
University of Alabama at Birmingham, University of Texas Southwestern Medical Center,
Medical College of Wisconsin, University of Pittsburgh, Oregon Health and Science University, University of Washington

PRAGMATIC AIRWAY RESUSCITATION TRIAL

ROC

Objective

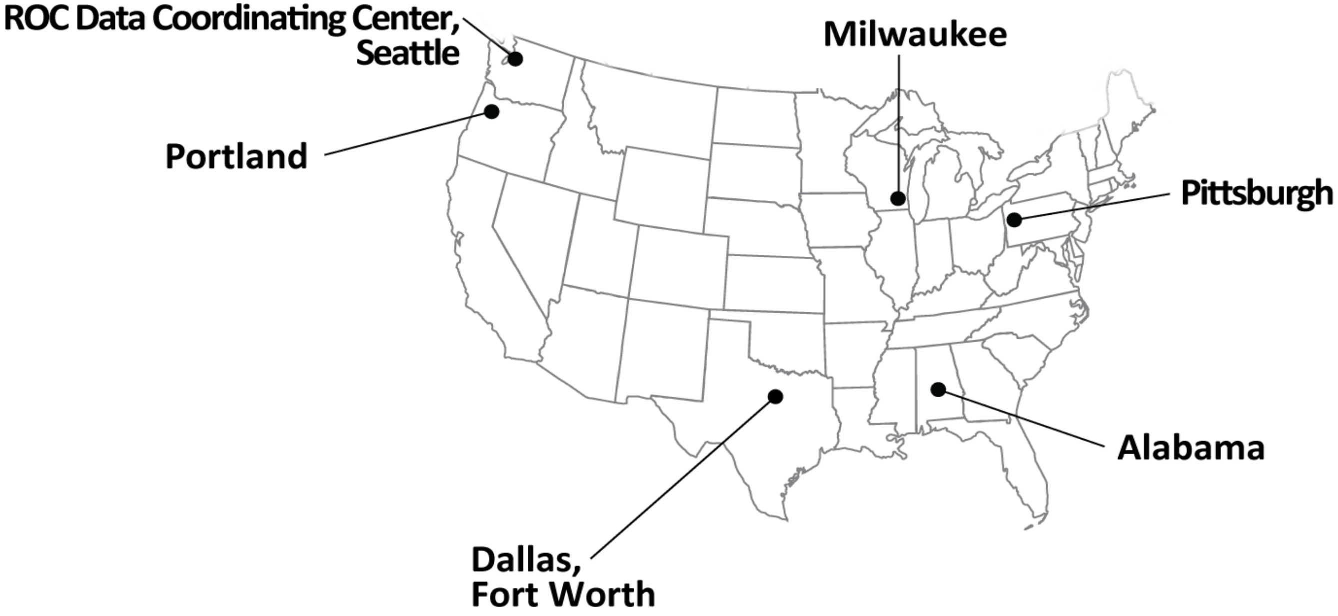
- **Compare effectiveness of initial laryngeal tube (LT) vs. initial ETI upon outcomes in adult OHCA**

PRAGMATIC AIRWAY RESUSCITATION TRIAL

ROC

Design

- **Multicenter cluster randomized trial with crossover**
- **Exception from Informed Consent**
  - 21 CFR 50.24
- **27 EMS agencies**
  - Alabama
  - Dallas-Fort Worth
  - Milwaukee
  - Pittsburgh
  - Portland



Funding Requirements

- **NHLBI program for low-cost pragmatic clinical trials**
- **Pragmatic emphasis**
  - Adherence to standard practices
  - Focus on outcomes
  - Less emphasis on mechanisms
- **Capped funding ($2.35M)**
- **US sites only**

ROC RESUSCITATION OUTCOMES CONSORTIUM

Enrollment Criteria

Inclusion

- Adult out-of-hospital cardiac arrest
- Treated by EMS
- Requiring advanced airway or BVM

Exclusion

- Children
- Pregnant women
- Prisoners
- Trauma
- Interfacility Transports
- Initial care by non-study EMS agency
- “Do not enroll” bracelet

Interventions

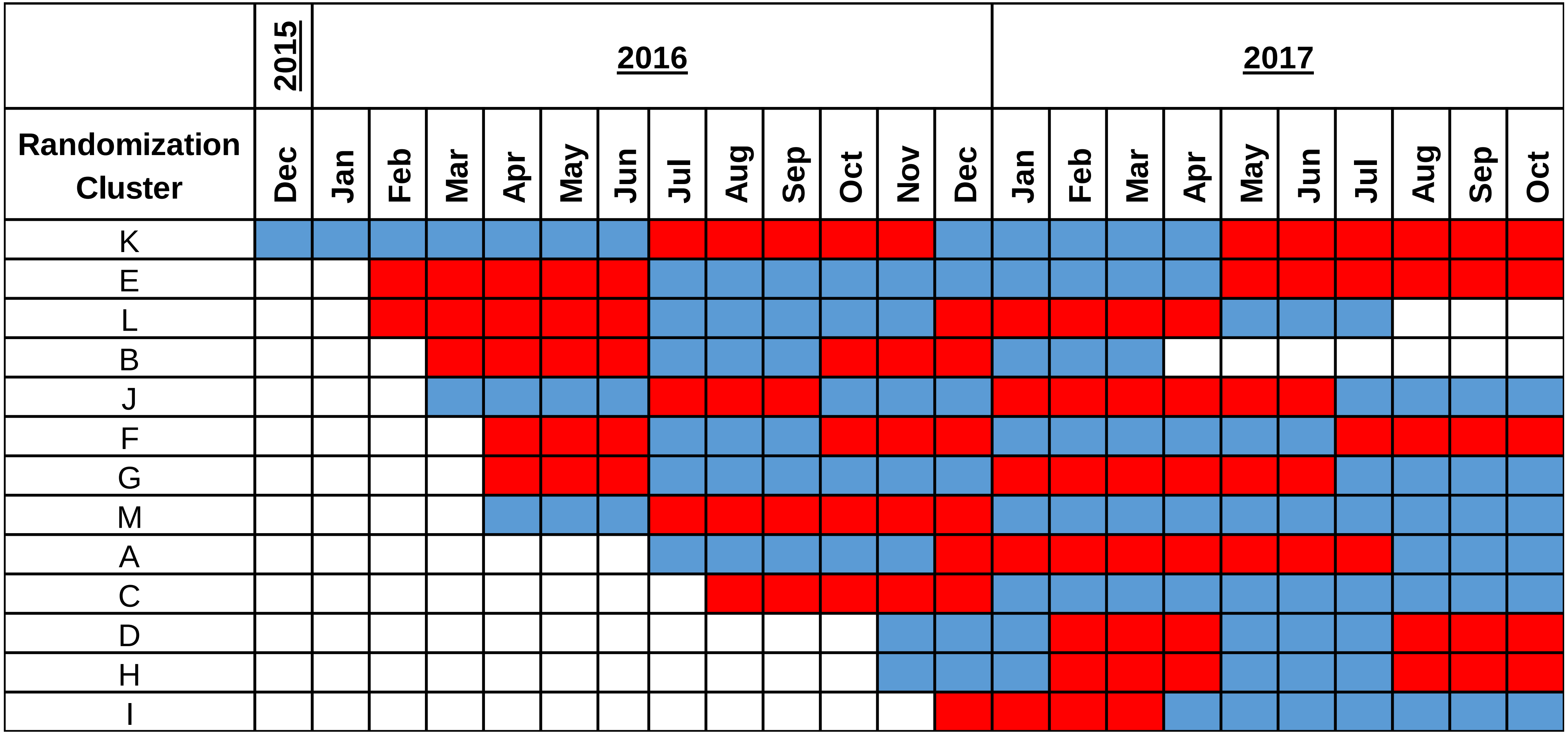
Adult Out-of-Hospital Cardiac Arrest

Laryngeal Tube
Advanced EMS: LT
Basic EMS: BVM (or LT)

Endotracheal Intubation
Advanced EMS: ETI
Basic EMS: BVM

CONTINUE RESUSCITATION

Cluster Randomization with Crossover



LT
ETI

Cluster-Crossover Schedule

Outcomes

- **Primary outcome → <u>72-hour survival</u>**
  - Pragmatic considerations
  - Limitations of funding
- **Secondary outcomes**
  - ROSC on ED arrival
  - Survival to hospital discharge
  - Favorable neurologic outcome on hospital discharge (MRS≤3)
  - Airway management course, adverse events

Data Analysis

- **Intention-to-treat**
  - Generalized estimating equations
  - Accounted for randomization cluster and interim analyses
- **Other analyses**
  - *A priori* defined subgroups
  - *Per-protocol* and *as-treated* analyses
  - *Post-hoc* multivariable adjusted analyses

- **Sample size estimate**
  - Data from ROC PRIMED trial
  - Power 85%, alpha 0.05, 5% loss in precision due to clustering, <u>4.5%</u> difference in 72h survival
  - Estimated minimum sample size 2,612
  - Increased sample size to <u>**3,000**</u>

RESUSCITATION OUTCOMES CONSORTIUM

Results

56 Cluster Enrollment Periods

30 LT Periods
1,968 Patients Screened

26 ETI Periods
1,872 Patients Screened

463 Patients Excluded

373 Patients Excluded

1,505 Patients Assigned to LT

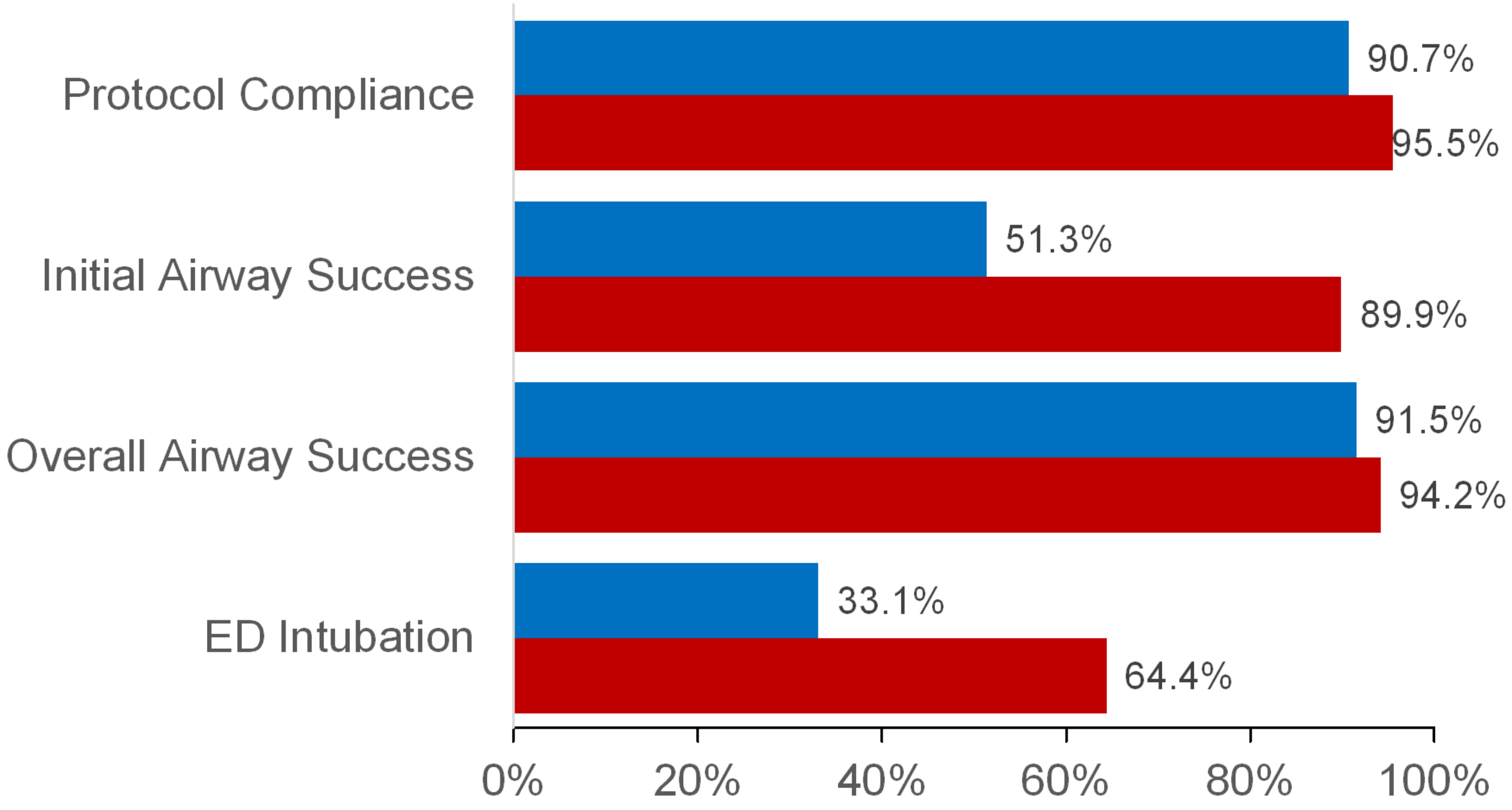
1,499 Patients Assigned to ETI

Patient Characteristics

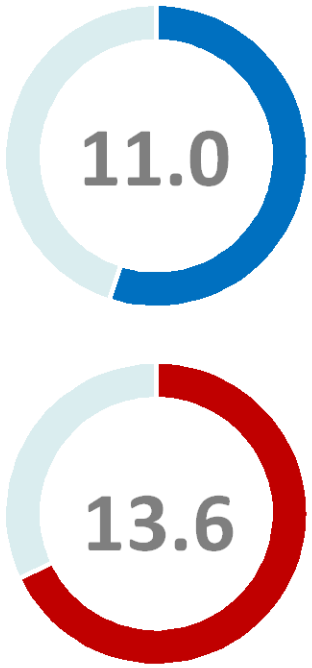
Characteristic	LT N=1,505	ETI N=1,499
Age – years, median (IQR)	64 (53, 76)	64 (53, 76)
Male	61.7%	60.1%
EMS Witnessed Arrest	13.3%	12.8%
Bystander Witnessed Arrest	37.7%	37.8%
Bystander CPR	55.5%	55.4%
EMS Dispatch-to-Arrival – minutes, med (IQR)	2.1 (1.1, 3.8)	2.1 (1.0, 3.7)
Shockable ECG Rhythm	20.0%	18.0%
Epinephrine Given	92.0%	93.7%
Transported to Hospital	60.2%	59.3%
Hospital Therapeutic Hypothermia	52.6%	46.3%
Hospital Coronary Catheterization	23.7%	18.3%

Similar Between Groups

Airway Management Characteristics



Arrive → Airway Start (min)



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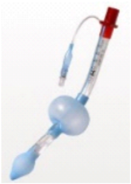
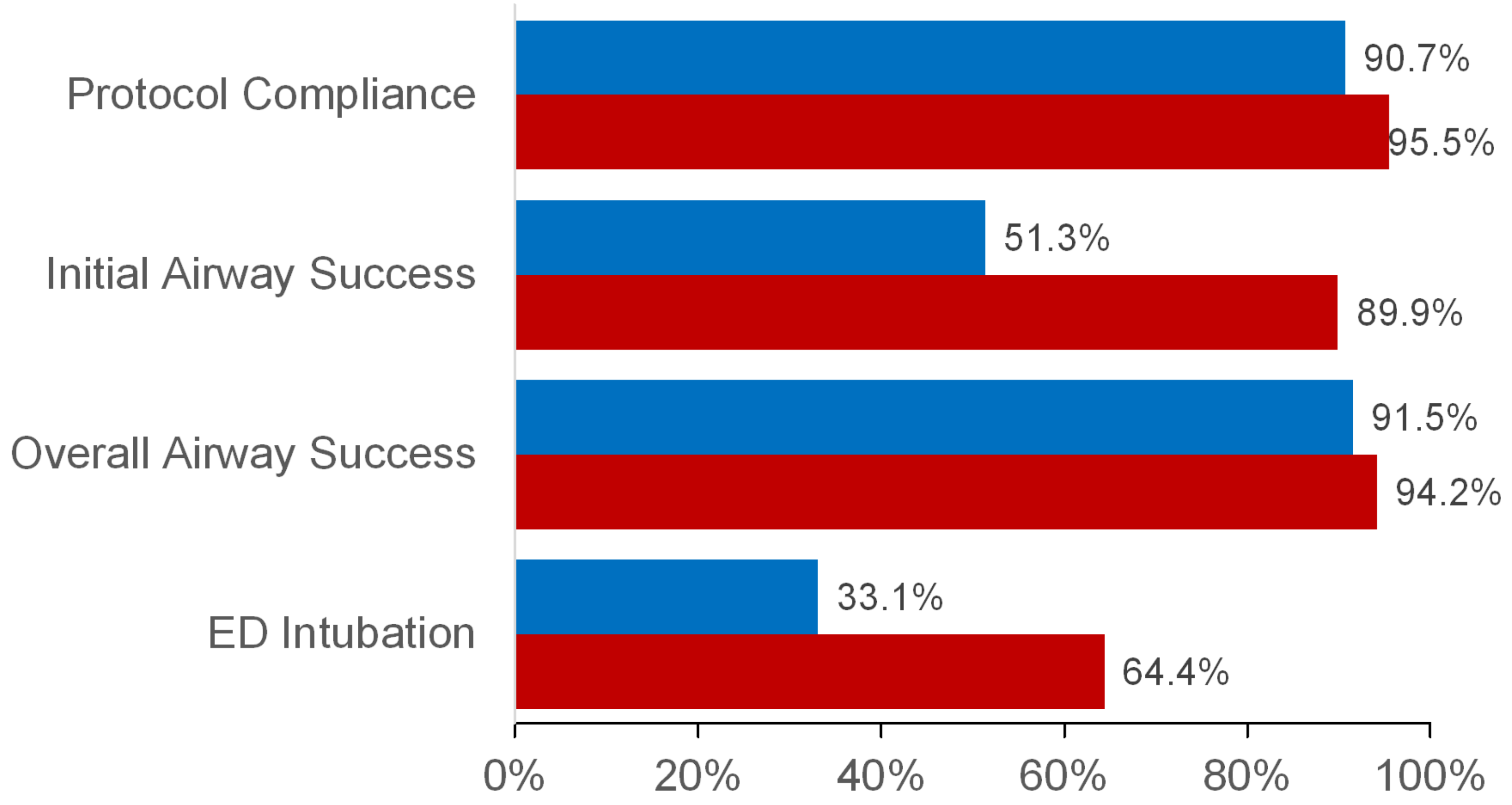
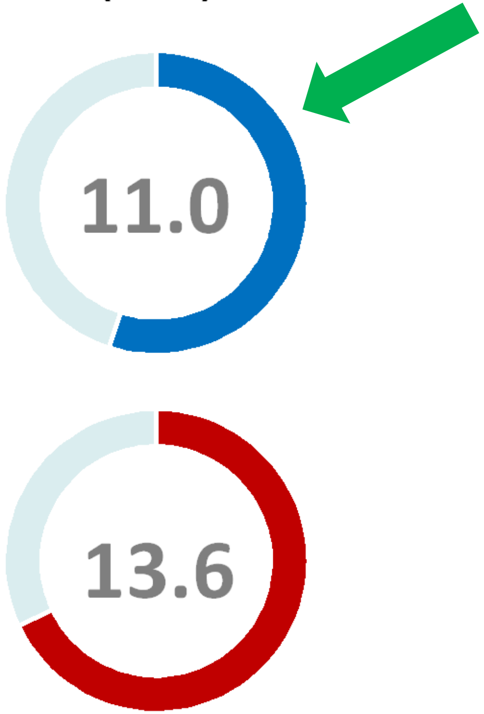


ETI

Airway Management Characteristics



Arrive → Airway Start (min)



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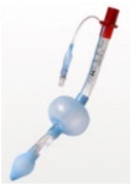
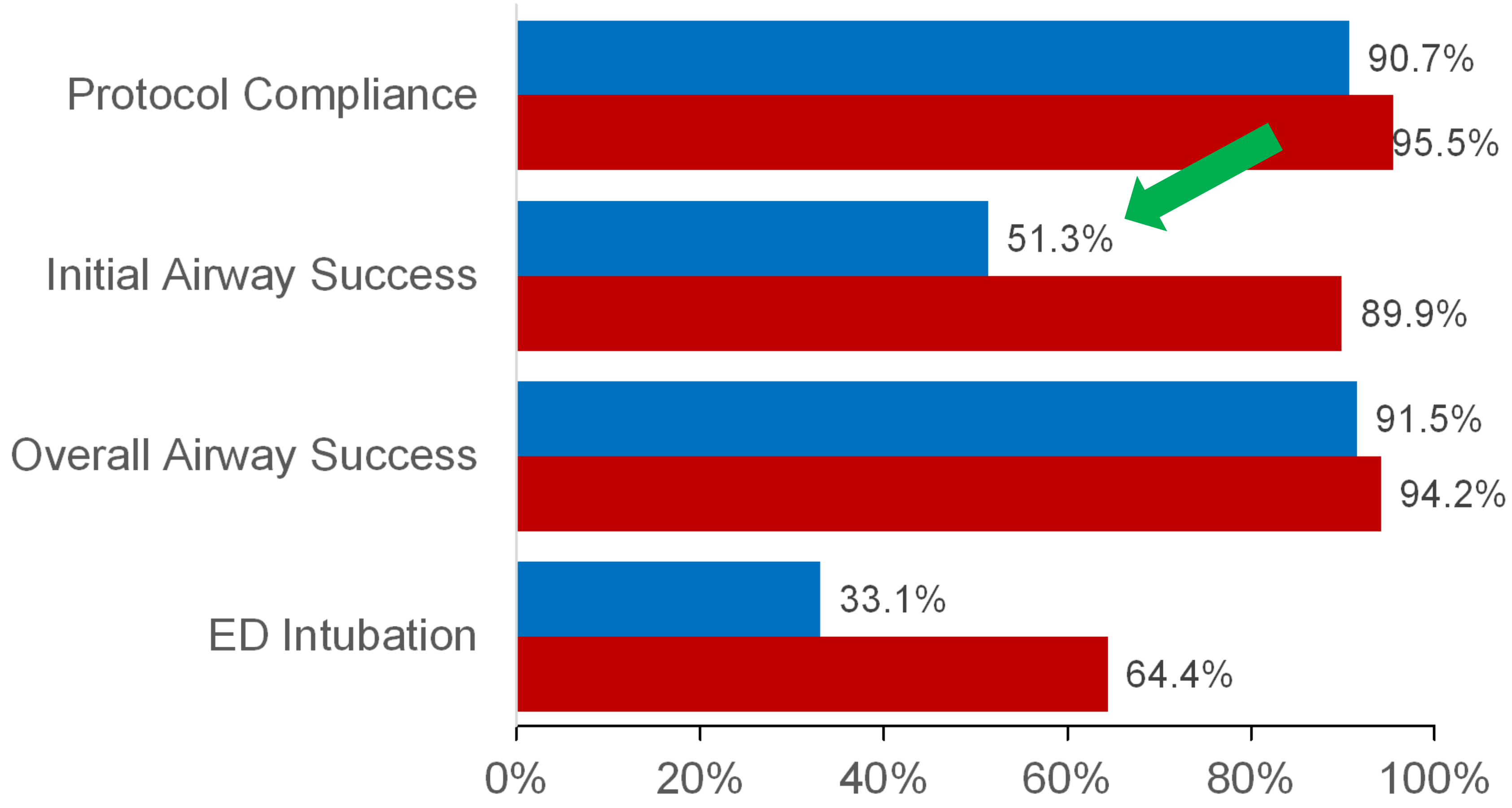
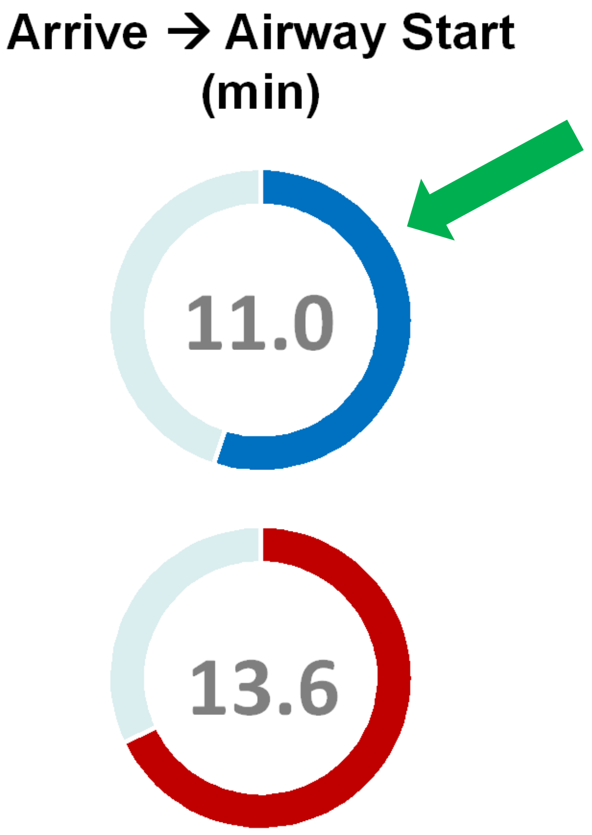


ETI

Airway Management Characteristics





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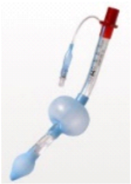
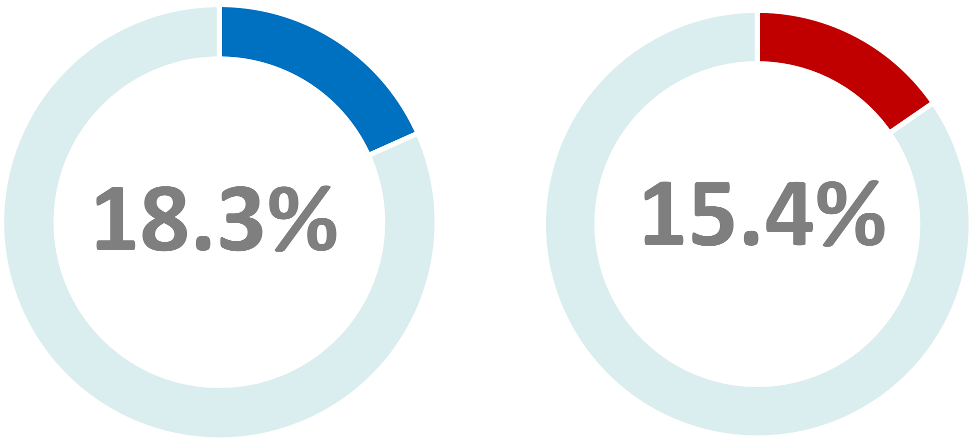


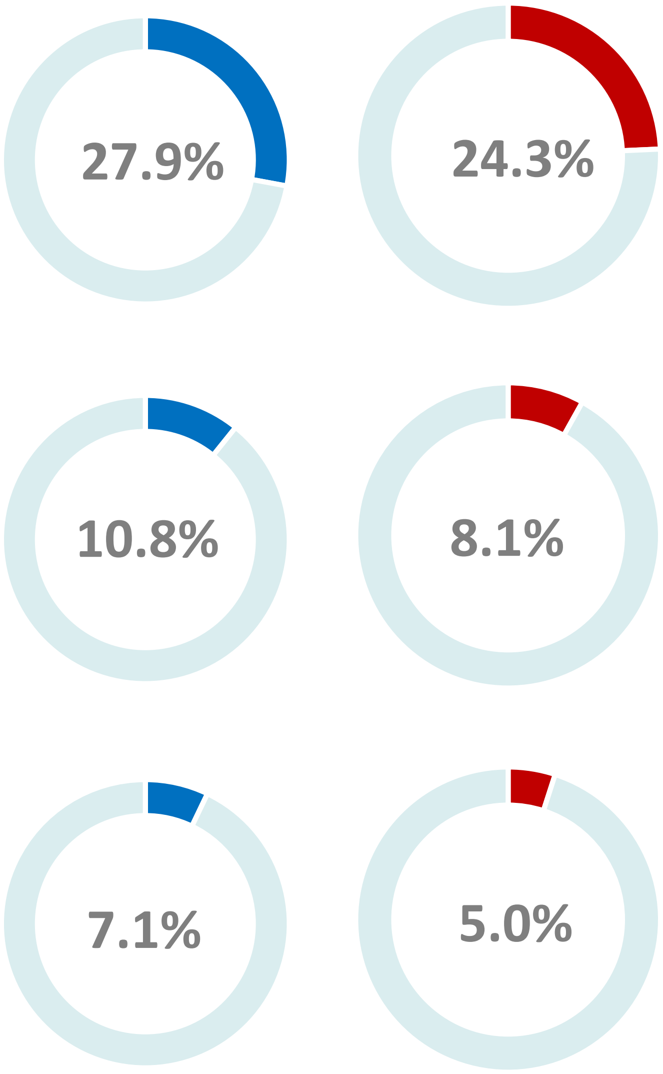
ETI

Primary and Secondary Outcomes

72h Survival



Δ = 2.9% (0.2-5.6%)
P=0.04



ROSC
Δ = 3.6% (0.3-6.8%)
P=0.03

Hospital Discharge
Δ = 2.7 (0.6-4.8)
P=0.01

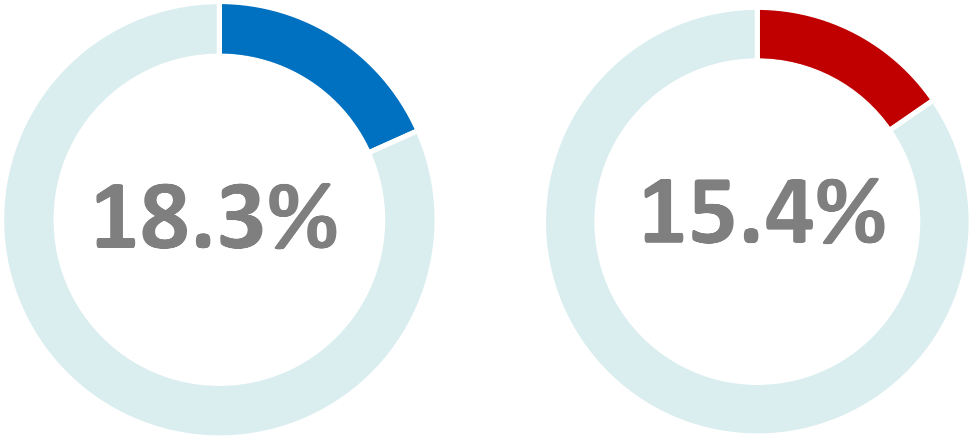
Favorable Neuro Status
Δ = 2.1% (0.3-3.8%)
P=0.02

LT

ETI

Primary and Secondary Outcomes

72h Survival



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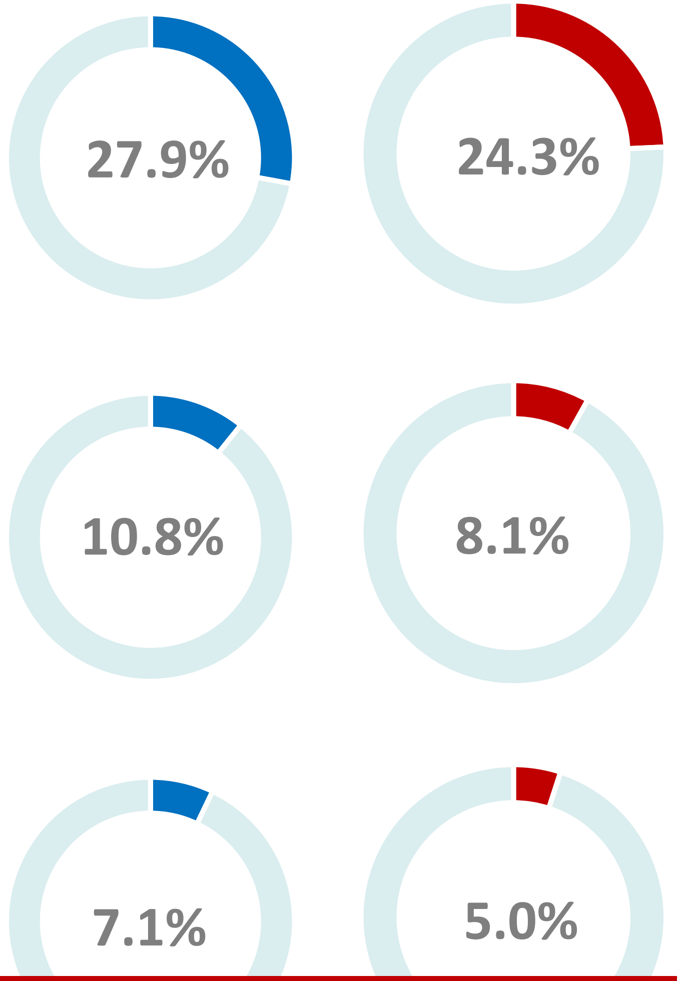

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Hospital Discharge
Δ = 2.7 (0.6-4.8)
P=0.01

Favorable Neuro Status
Δ = 2.1% (0.3-3.8%)
P=0.02

LT


ETI


"LT better than ETI over all outcomes"

Airways-2 Trial

Benger, et al, JAMA 2018

Research

JAMA | Original Investigation

Effect of a Strategy of a Supraglottic Airway Device vs Tracheal Intubation During Out-of-Hospital Cardiac Arrest on Functional Outcome
The AIRWAYS-2 Randomized Clinical Trial

Jonathan R. Benger, MD; Kim Kirby, MRes; Sarah Black, DClinRes; Stephen J. Brett, MD; Madeleine Clout, BSc; Michelle J. Lazaroo, MSc; Jerry P. Nolan, MBChB; Barnaby C. Reeves, DPhil; Maria Robinson, MOst; Lauren J. Scott, MSc; Helena Smartt, PhD; Adrian South, BSc (Hons); Elizabeth A. Stokes, DPhil; Jodi Taylor, PhD; Matthew Thomas, MBChB; Sarah Voss, PhD; Sarah Wordsworth, PhD; Chris A. Rogers, PhD

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Supplemental content

IMPORTANCE The optimal approach to airway management during out-of-hospital cardiac arrest is unknown.

OBJECTIVE To determine whether a supraglottic airway device (SGA) is superior to tracheal intubation (TI) as the initial advanced airway management strategy in adults with nontraumatic out-of-hospital cardiac arrest.

DESIGN, SETTING, AND PARTICIPANTS Multicenter, cluster randomized clinical trial of paramedics from 4 ambulance services in England responding to emergencies for approximately 21 million people. Patients aged 18 years or older who had a nontraumatic out-of-hospital cardiac arrest and were treated by a participating paramedic were enrolled automatically under a waiver of consent between June 2015 and August 2017; follow-up ended in February 2018.

INTERVENTIONS Paramedics were randomized 1:1 to use TI (764 paramedics) or SGA (759 paramedics) as their initial advanced airway management strategy.

MAIN OUTCOMES AND MEASURES The primary outcome was modified Rankin Scale score at hospital discharge or 30 days after out-of-hospital cardiac arrest, whichever occurred sooner. Modified Rankin Scale score was divided into 2 ranges: 0-3 (good outcome) or 4-6 (poor outcome; 6 = death). Secondary outcomes included ventilation success, regurgitation, and aspiration.

RESULTS A total of 9296 patients (4886 in the SGA group and 4410 in the TI group) were enrolled (median age, 73 years; 3373 were women [36.3%]), and the modified Rankin Scale score was known for 9289 patients. In the SGA group, 311 of 4882 patients (6.4%) had a good outcome (modified Rankin Scale score range, 0-3) vs 300 of 4407 patients (6.8%) in the TI group (adjusted risk difference [RD], −0.6% [95% CI, −1.6% to 0.4%]). Initial ventilation was successful in 4255 of 4868 patients (87.4%) in the SGA group compared with 3473 of 4397 patients (79.0%) in the TI group (adjusted RD, 8.3% [95% CI, 6.3% to 10.2%]). However, patients randomized to receive TI were less likely to receive advanced airway management (3419 of 4404 patients [77.6%] vs 4161 of 4883 patients [85.2%] in the SGA group). Two of the secondary outcomes (regurgitation and aspiration) were not significantly different between groups (regurgitation: 1268 of 4865 patients [26.1%] in the SGA group vs 1072 of 4372 patients [24.5%] in the TI group; adjusted RD, 1.4% [95% CI, −0.6% to 3.4%]; aspiration: 729 of 4824 patients [15.1%] vs 647 of 4337 patients [14.9%], respectively; adjusted RD, 0.1% [95% CI, −1.5% to 1.8%]).

CONCLUSIONS AND RELEVANCE Among patients with out-of-hospital cardiac arrest, randomization to a strategy of advanced airway management with a supraglottic airway device compared with tracheal intubation did not result in a favorable functional outcome at 30 days.

TRIAL REGISTRATION ISRCTN Identifier: 08256118

JAMA. 2018;320(8):779-791. doi:10.1001/jama.2018.11597

Author Affiliations: Author affiliations are listed at the end of this article.

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AIRWAYS 2

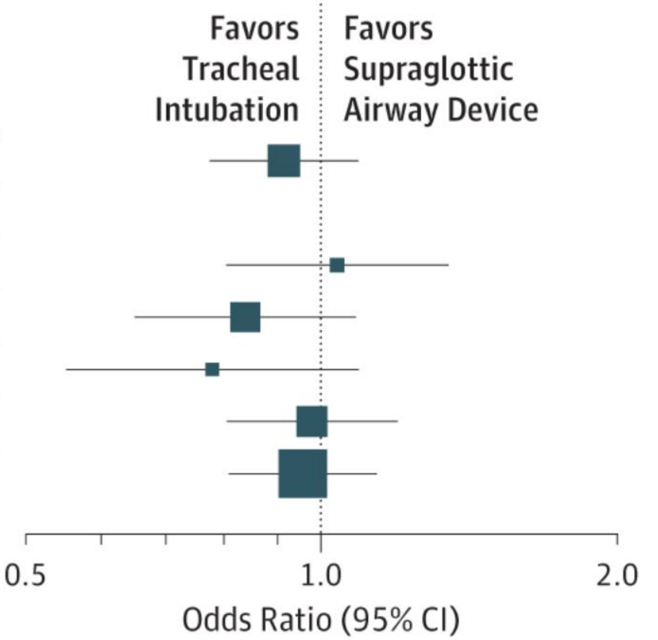
Airways-2 Design

- **RCT**
- **United Kingdom**
  - 4 EMS agencies
  - Population 21 million
  - 40% of UK population
- **Adult OHCA**
- **Intubation vs i-gel**

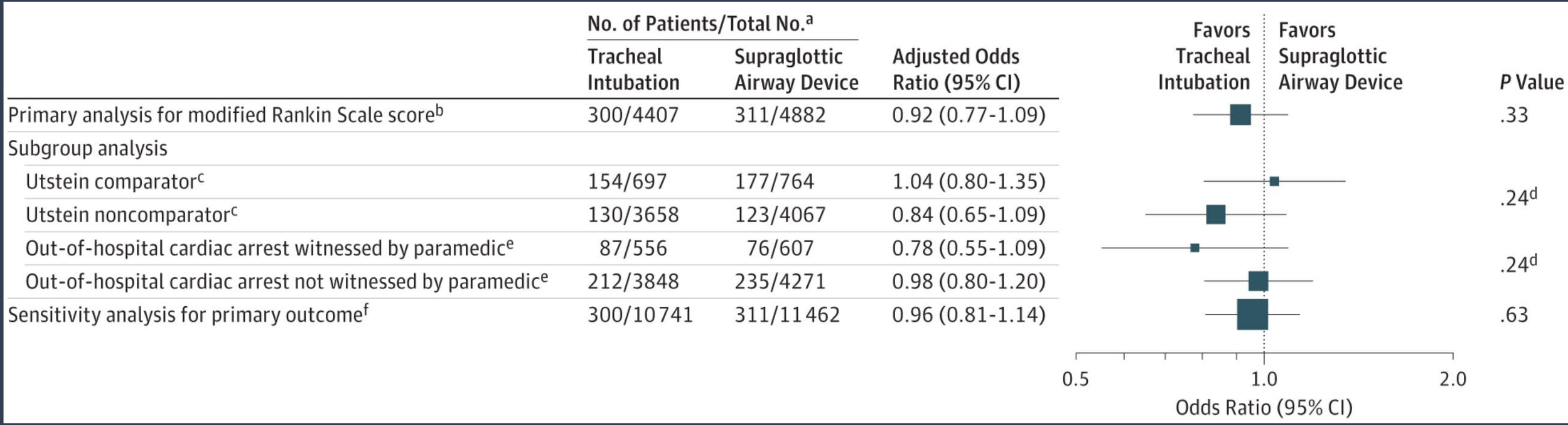
- **Cluster randomized**
  - By study paramedic
  - N=1,523 medics
- **Hospital Survival with Favorable Neuro Status**
- **Estimated n=9,070 patients**
- **June 2015 – August 2017**

Airways-2 – Primary Findings

	No. of Patients/Total No.[a]				
	Tracheal Intubation	Supraglottic Airway Device	Adjusted Odds Ratio (95% CI)		*P* Value
Primary analysis for modified Rankin Scale score[b]	300/4407	311/4882	0.92 (0.77-1.09)		.33
Subgroup analysis					
Utstein comparator[c]	154/697	177/764	1.04 (0.80-1.35)		.24[d]
Utstein noncomparator[c]	130/3658	123/4067	0.84 (0.65-1.09)		
Out-of-hospital cardiac arrest witnessed by paramedic[e]	87/556	76/607	0.78 (0.55-1.09)		.24[d]
Out-of-hospital cardiac arrest not witnessed by paramedic[e]	212/3848	235/4271	0.98 (0.80-1.20)		
Sensitivity analysis for primary outcome[f]	300/10 741	311/11 462	0.96 (0.81-1.14)		.63



Airways-2 – Primary Findings



	No. of Patients/Total No.[a]				
	Tracheal Intubation	Supraglottic Airway Device	Adjusted Odds Ratio (95% CI)	Favors Tracheal Intubation / Favors Supraglottic Airway Device	P Value
Primary analysis for modified Rankin Scale score[b]	300/4407	311/4882	0.92 (0.77-1.09)		.33
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“No difference between i-gel and ETI”

Important Secondary Finding

- **~18% received BVM only**
- **When limited to 7,576 receiving i-Gel or ETI:**
  - i-gel → 163 of 4,158 (3.9%) good outcome
  - ETI → 88 of 3,418 (2.6%) good outcome
  - Risk difference 1.4% (95% CI: 0.5-2.2%)

Important Secondary Finding

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- **When limited to 7,576 receiving i-Gel or ETI:**
  - i-gel → 163 of 4,158 (3.9%) good outcome
  - ETI → 88 of 3,418 (2.6%) good outcome
  - Risk difference 1.4% (95% CI: 0.5-2.2%)

"Per-Protocol → i-gel better than ETI"

Cardiac Arrest Airway Management Trial (CAAM)

Jabre, et al., JAMA 2018

Research

JAMA | Original Investigation

Effect of Bag-Mask Ventilation vs Endotracheal Intubation During Cardiopulmonary Resuscitation on Neurological Outcome After Out-of-Hospital Cardiorespiratory Arrest

A Randomized Clinical Trial

Patricia Jabre, MD, PhD; Andrea Penaloza, MD, PhD; David Pinero, MD; Francois-Xavier Duchateau, MD; Stephen W. Borron, MD, MS; Francois Javaudin, MD; Olivier Richard, MD; Diane de Longueville, MD; Guillem Bouilleau, MD; Marie-Laure Devaud, MD; Matthieu Heidet, MD, MPH; Caroline Lejeune, MD; Sophie Fauroux, MD; Jean-Luc Greingor, MD; Alessandro Manara, MD; Jean-Christophe Hubert, MD; Bertrand Guihard, MD; Olivier Vermylen, MD; Pascale Lievens, MD; Yannick Auffret, MD; Celine Maisondieu, MD; Stephanie Huet, MD; Benoît Claessens, MD; Frederic Lapostolle, MD, PhD; Nicolas Javaud, MD, PhD; Paul-Georges Reuter, MD, MS; Elinor Baker, MD; Eric Vicaut, MD, PhD; Frédéric Adnet, MD, PhD

IMPORTANCE Bag-mask ventilation (BMV) is a less complex technique than endotracheal intubation (ETI) for airway management during the advanced cardiac life support phase of cardiopulmonary resuscitation of patients with out-of-hospital cardiorespiratory arrest. It has been reported as superior in terms of survival.

OBJECTIVES To assess noninferiority of BMV vs ETI for advanced airway management with regard to survival with favorable neurological function at day 28.

DESIGN, SETTINGS, AND PARTICIPANTS Multicenter randomized clinical trial comparing BMV with ETI in 2043 patients with out-of-hospital cardiorespiratory arrest in France and Belgium. Enrollment occurred from March 9, 2015, to January 2, 2017, and follow-up ended January 26, 2017.

INTERVENTION Participants were randomized to initial airway management with BMV (n = 1020) or ETI (n = 1023).

MAIN OUTCOMES AND MEASURES The primary outcome was favorable neurological outcome at 28 days defined as cerebral performance category 1 or 2. A noninferiority margin of 1% was chosen. Secondary end points included rate of survival to hospital admission, rate of survival at day 28, rate of return of spontaneous circulation, and ETI and BMV difficulty or failure.

RESULTS Among 2043 patients who were randomized (mean age, 64.7 years; 665 women [32%]), 2040 (99.8%) completed the trial. In the intention-to-treat population, favorable functional survival at day 28 was 44 of 1018 patients (4.3%) in the BMV group and 43 of 1022 patients (4.2%) in the ETI group (difference, 0.11% [1-sided 97.5% CI, −1.64% to infinity]; *P* for noninferiority = .11). Survival to hospital admission (294/1018 [28.9%] in the BMV group vs 333/1022 [32.6%] in the ETI group; difference, −3.7% [95% CI, −7.7% to 0.3%]) and global survival at day 28 (55/1018 [5.4%] in the BMV group vs 54/1022 [5.3%] in the ETI group; difference, 0.1% [95% CI, −1.8% to 2.1%]) were not significantly different. Complications included difficult airway management (186/1027 [18.1%] in the BMV group vs 134/996 [13.4%] in the ETI group; difference, 4.7% [95% CI, 1.5% to 7.9%]; *P* = .004), failure (69/1028 [6.7%] in the BMV group vs 21/996 [2.1%] in the ETI group; difference, 4.6% [95% CI, 2.8% to 6.4%]; *P* < .001), and regurgitation of gastric content (156/1027 [15.2%] in the BMV group vs 75/999 [7.5%] in the ETI group; difference, 7.7% [95% CI, 4.9% to 10.4%]; *P* < .001).

CONCLUSIONS AND RELEVANCE Among patients with out-of-hospital cardiorespiratory arrest, the use of BMV compared with ETI failed to demonstrate noninferiority or inferiority for survival with favorable 28-day neurological function, an inconclusive result. A determination of equivalence or superiority between these techniques requires further research.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT02327026

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Supplemental content

CME Quiz at jamanetwork.com/learning

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CAAM Design

- **RCT**
- **France and Belgium SAMUs**
  - 20 EMS centers
  - MD + RN + Driver
- **Adult OHCA**
- **BVM vs. ETI**
  - Intervention by “medical team”
  - ETI post-ROSC
- **Per-Patient Randomization**
  - Sealed envelopes
- **28d Survival with Favorable Neuro Status**
- **“Non-inferiority” design**
  - 1% Non-inferiority margin
  - Estimated n=2,000
- **March 2015 - Jan 2017**

Primary Result
28-day Survival with Favorable Neuro Status (CPC 1-2)

- BVM → 44 / 1018 (4.3%)
- ETI → 43 / 1022 (4.2%)
- Difference = 0.11% (1-sided 97.5% CI: -1.64% to infinity)
- Non-inferiority p=0.11

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"This is an uninterpretable result…"

Very Important Secondary Findings

Table 3. Airway Management Adverse Events Analysis

Safety Population	BMV Group	ETI Group	Absolute Difference, BMV(%) − ETI(%) (95% CI)	*P* Value[a]
BMV or ETI Difficulty				
BMV VAS, median (IQR), mm[b]	20 (5-55)	NA	NA	NA
Intubation Difficulty Scale score, median (IQR)	NA	1 (0-4)	NA	NA
Rate of airway management difficulty, No./total No. (%)[c]	186/1027 (18.1)	134/996 (13.4)	4.7 (1.5-7.9)	.004
BMV or ETI failure, No./total No. (%)	69/1028 (6.7)	21/996 (2.1)	4.6 (2.8-6.4)	<.001
BMV or ETI Complications, No. (%)	**n = 1027**	**n = 999**		
Regurgitation of gastric content	156 (15.2)	75 (7.5)	7.7 (4.9-10.4)	<.001
Mainstem intubation[d]	NA	20 (2.0)	NA	NA
Recognized esophageal intubation[e]	NA	102 (10.2)	NA	NA
Dental injury	NA	7 (0.7)	NA	NA
Extubation	NA	5 (0.5)	NA	NA

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Summing Up the Trials

Characteristic	PART	Airways-2	CAAM
Setting	USA	UK	France, Belgium
Comparison	LT vs. ETI	i-gel vs. ETI	BVM vs. ETI
Practitioners	Paramedics, Some EMTs	Paramedics	Physicians (SAMUs)
Sample Size	3,000	9,296	2,043
Randomization	Cluster Randomized by EMS Agencies	Cluster Randomized by Medic	Per Patient (sealed envelopes)
Primary Outcome	72-hour Survival	Hospital Survival w/Favorable Neuro Status	28-Day Survival w/Favorable Neuro Status
BVM-only rate	~12%	~18%	N/A
Primary Finding	**LT better than ETI**	**No difference between i-gel and ETI**	**Inconclusive**
Important Secondary Findings	Low ETI Success Rate	i-gel Better Than ETI	BVM → Poorer Ventilation, Higher Aspiration

The Big Picture

- PART “SGA (LT) is better than ETI”
- Airways-2 “At best, ETI is no better than SGA (i-Gel)”
- CAAM “BVM is <u>not</u> the answer”

Next Chapters

- **Mechanistic data**
  - Chest compressions
  - Lung ventilations
- **SGA Safety Data**
- **Implementation strategies**
- **Other patient groups**
  - Trauma (PACT)
  - Peds (Pedi-PART)
- **Hospital airway practices**

Questions?

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